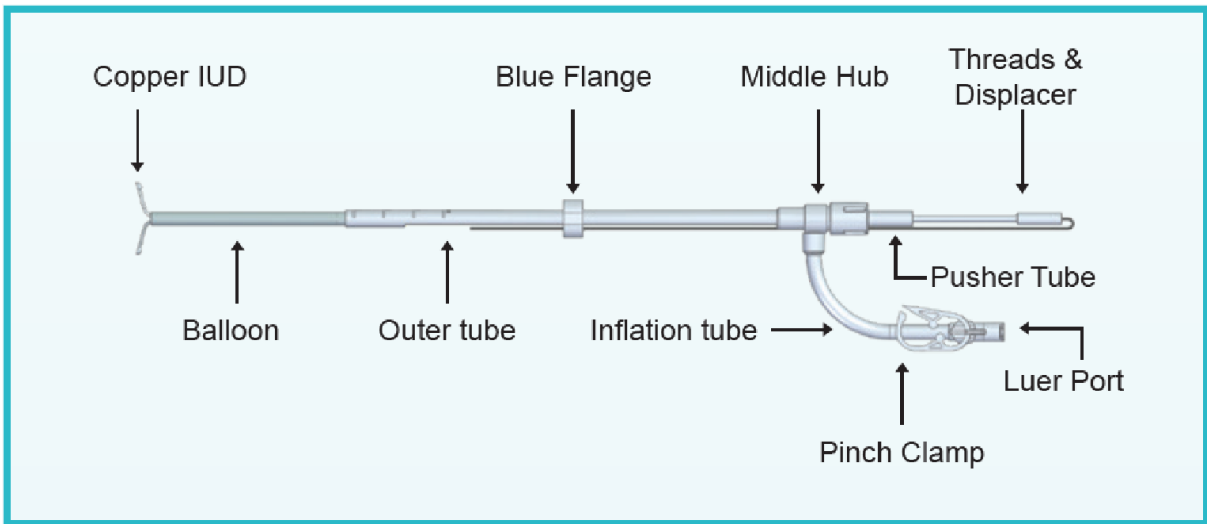
Summary of Safety and Clinical Performance

Intrauterine Contraceptive Device- Cu 380 & Mini Cu 380 , Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound



Cu 380/ Mini Cu 380 with CrossGlide Inserter

PREGNA INTERNATIONAL LTD.
Plot No. 219, Survey No. 168,
Dabhel Co. Op. Ind. Soc. Ltd.,
Dabhel, Daman (U.T.)- 396210, India
Phone : +(91)-(260)-3206372/3207093.
Fax : +(91)-(22)-23513484.
www.pregna.com

1. Introduction

The Regulation (EU) 2017/745 on medical devices requires that the manufacturer shall draw up a summary of safety and clinical performance (SSCP) for implantable devices and for class III devices, other than custom-made or investigational devices. The SSCP shall be validated by a notified body (NB) and made available to the public via the European database on medical devices (Eudamed).

The SSCP is intended to provide public access to an updated summary of clinical data and other information about the safety and clinical performance of the medical device. The SSCP will be an important source of information for intended users – both healthcare professionals and if relevant for patients. It is one of several means intended to fulfil the objectives of the Medical Device Regulation (MDR) to enhance transparency and provide adequate access to information.

The SSCP is not intended to:

- Give general advice on the diagnosis or treatment of particular medical conditions, nor
- Replace the instructions for use (IFU) as the main document that will be provided to ensure the safe use of a particular device, nor
- Replace the mandatory information on implant cards or in any other mandatory documents.

The main purpose of this document is to guide the presentation, content and validation of the SSCP. The word “shall” is used when there is a corresponding “shall” in the MDR, otherwise “should” or “recommended” etc. is used to indicate the interpretation of the MDR.

2. Device identification and general information

2.1	Device trade name(s)	Intrauterine Contraceptive Device- Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound
		Brand Names: • Copper Y 380 • Copper Y Mini 380 • Yanae Cu 380 with CrossGlide Inserter • Copper Y Cu 380 with Loader • Yanae Mini Cu 380 with CrossGlide Inserter • Copper Y Mini Cu 380 with Loader • Cu 380 • Mini Cu 380

2.2	Manufacturer's name and address	PREGNA INTERNATIONAL LTD. Plot No. 219, Survey No. 168, Dabhel Co. Op. Ind. Soc. Ltd., Dabhel, Daman (U.T.)- 396210, India Phone: +(91)-(260)-3206372/3207093. Fax: +(91)-(22)-23513484. www.pregna.com
2.3	Manufacturer's single registration number (SRN)	IN-MF-000010389
2.4	Basic UDI-DI	
i.	Cu 380	89040453pregnaCu3800000YA
ii.	Mini Cu 380	
2.5	Medical device nomenclature description / text	Cu 380 is another version of the commonly used intrauterine contraceptive device Cu T 380A wherein the T frame is substituted with flexible "Y" frame which helps insertion and removal of IUD less painful. The copper wire used in Cu 380 is the same which is used in Pregna other IUDs. The copper quality and the source have been approved in consultation process by DNV GL. The number 380 denotes the surface area of copper available on the device. Copper Y mini Cu 380, offer almost complete protection against pregnancy having shelf life 5 years and it remains effective for period of 5 years Copper Y mini Cu 380 is an another version of the commonly used intrauterine contraceptive device Copper T Cu 380A. The difference made is using Mini frame in place of normal frame. The purity and source of copper used is the same as the copper used in the manufacturer of other IUD's by the company. The copper quality and the source have been approved in DNV Oslo. The number 380 denotes the surface area of copper available on the device. Copper Y mini Cu 380 is consists of frame made up of polyethylene with Barium Sulphate. The body bears the coil of copper wire on its vertical arm. A monofilament suture thread made up of Nylon or HDPE is tied to the end portion of frame at the bottom of vertical arm. This suture thread facilitates periodic checking by the user and also facilitates removal of device. Copper Y mini Cu 380 is packed in individual sterile pouch. Each pouch contains one unit of Copper Y mini Cu 380 along with other components like insertion tube,

		flange and Solid rod (used for insertion purpose) and label insert. All the components are packed in either Film/Film pouch or Tyvek/Film pouch. The pouch is then gamma sterilized and can be stored for up to five years. Copper Y mini Cu 380 is inserted into the uterus by the physician/doctor. A plastic string tied to the end of the IUD hangs down through the cervix into the vagina which can be used to check/verify that the IUD is in place by feeling the string. The string is also used by physician/doctor to remove the IUD.
2.6	Class of device	Class III, Rule 14 as per Annex VIII of MDR 2017/745
2.7	Year when the first certificate (CE) was issued covering the device	2006
2.8	Authorized representative if applicable; name and the SRN	Name: Medical Technology Promedt Consulting GmbH Address: Ernst-Heckel-Straße 7, 66386 St. Ingbert,Germany Phone: +49 6894 581020 Email: ear@mt-procons.com Website: https://www.mt-procons.com/ SRN: DE-AR-000000085
2.9	NB's name (the NB that will validate the SSCP) and the NB's single identification number	DNV Product Assurance AS Veritasveien 3, 1363 Høvik, Norway www.dnv.com Notified Body No: 2460

3. Intended use of the device

3.1 Intended purpose

Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound offer almost complete protection against pregnancy for period of 5 years.

3.2 Indication(s) and target population(s)

i. Medical Indications

Intrauterine contraceptive devices are indicated for use in women of child bearing age. It is used for contraception in female which is reversible means fertility (Pregnancy) can be achieved by removing Cu 380, Mini Cu 380.

ii. Target Population

Women of child bearing age.

3.3 User Qualification

The device will be inserted by Trained Medical Professionals.

3.4 Contraindications and/or limitations

Contraindication (Absolute)

- Malignant diseases of the genital tract
- Undiagnosed vaginal bleeding
- Pregnancy
- History of ectopic pregnancy or predisposing factors.
- Infections of the genital tract
- Sexually transmitted diseases during the last 12 months (except bacterial vaginitis,
- repeated herpes infection, Hepatitis B)
- Abortion with infection during the last 3 months, pelvic inflammatory disease
- Uterine malformations (congenital or acquired)
- Allergy to copper

Contraindication (Relative)

- Anemia
- Valvular heart disease
- Coagulation disorders
- Anti-inflammatory treatment
- Wilson's disease
- Multiple exposures to different sexual partners

4. Device description

4.1 Description of the device

Cu 380

Cu 380 was first introduced by Schering AG. Under the brand name Nova T Cu 380 in the year 2002.

Cu 380 is another version of the commonly used intrauterine contraceptive device Cu T 380A wherein the T frame is substituted with flexible "Y" frame which helps insertion and removal of IUD less painful.

The copper wire used in Cu 380 is the same which is used in Pregna other IUDs. The copper quality and the source have been approved in consultation process by DNV GL. The number 380 denotes the surface area of copper available on the device.

Copper Y Cu 380, offer almost complete protection against pregnancy having shelf life 5 years and it remains effective for period of 5 years

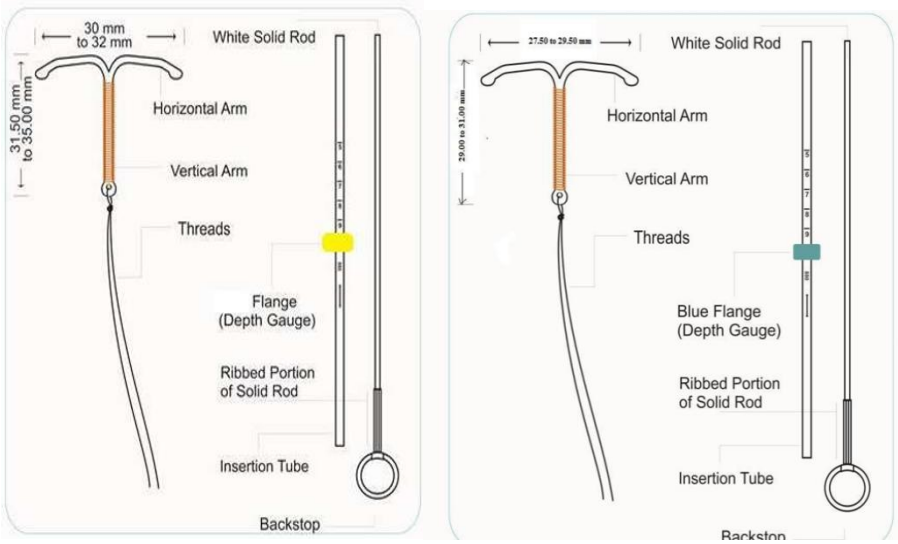
Mini Cu 380

Copper Y mini Cu 380 is another version of the commonly used intrauterine contraceptive device Copper T Cu 380A. The difference made is using Mini frame in place of normal frame. The purity and source of copper used is the same as the copper used in the manufacturer of other IUD's by the company. The copper quality and the source have been approved in DNV Oslo. The number 380 denotes the surface area of copper available on the device.

Copper Y mini Cu 380 consists of a frame made up of polyethylene with Barium Sulphate. The body bears the coil of copper wire on its vertical arm. A monofilament suture thread made up of Nylon or HDPE is tied to the end portion of the frame at the bottom of the vertical arm. This suture thread facilitates periodic checking by the user and also facilitates removal of devices.

Copper Y mini Cu 380 is packed in an individual sterile pouch. Each pouch contains one unit of Copper Y mini Cu 380 along with other components like insertion tube, flange and Solid rod (used for insertion purpose) and label insert. All the components are packed in either Film/Film pouch or Tyvek/Film pouch. The pouch is then gamma sterilized and can be stored for up to five years.

Copper Y mini Cu 380 is inserted into the uterus by the physician/doctor. A plastic string tied to the end of the IUD hangs down through the cervix into the vagina which can be used to check/verify that the IUD is in place by feeling the string. The string is also used by physician/doctor to remove the IUD.



Cu 380 **Mini Cu 380**

Cu 380 and Mini Cu 380 with Loader

IUD (Cu 380 & Mini Cu 380) with Loader consists of Y shaped frame made up of polyethylene with Barium Sulphate. The body (Cu 380 / Mini Cu 380) bears the coil of copper wire only on its vertical arm. A monofilament suture thread made up of Nylon is tied to the end portion of frame at the bottom of vertical arm. This suture thread facilitates periodic checking by the user and also facilitates removal of device.

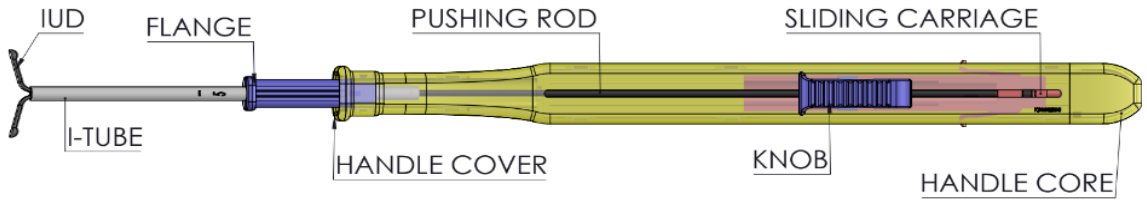
All the iuds with Loader are packed in individual sterile film-film pouch/Blister tray. Each sterile pouch/blister tray contains one unit of IUD along with Loader assembly (used for loading and insertion of Y Frame). The film-film pouch/blister tray is then gamma sterilized and can be stored for up to its defined shelf life.

IUD is inserted into the uterus by the physician/doctor. A suture string tied to the end of the IUD hangs down through the cervix into the vagina which can be used to check/verify that the IUD is in place by feeling the string. The string is also used by physician/doctor to remove the IUD.

Loader (Accessory)

The Loader is used for loading of the IUD into the insertion tube and releasing the IUD into the uterine cavity in aseptic condition. The loader consists of a handle core, handle cover, sliding core, sliding carriage, top-bottom slider knob, insertion tube, flange, and pushing rod. These all components are made up of biocompatible ABS (Acrylonitrile butadiene styrene) material. This is the same material

which is used in Pregna Model Etherena T Cu 380A. The iuds along with loader and label inserts are sealed in film-film pouches and gamma sterilized.



Cu 380/ Mini Cu 380 with Loader

YANAE Cu 380 with crossglide Inserter and YANAE Mini Cu 380 with crossglide Inserter

Cu 380 with crossglide Inserter consists of frame made up of polyethylene with Barium Sulphate. The body bears the coil of copper wire on its vertical arm. A monofilament suture thread made up of Nylon is tied to the end portion of frame at the bottom of vertical arm. This suture thread facilitates periodic checking by the user and also facilitates removal of device.

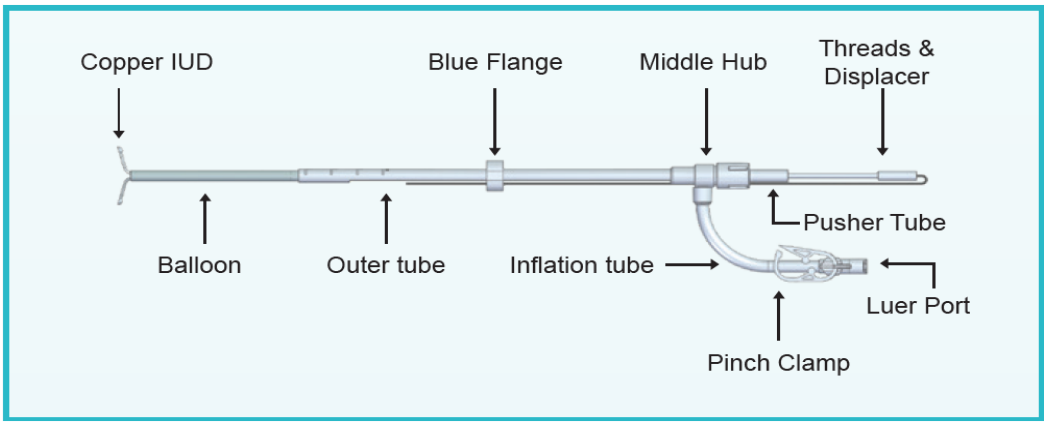
Cu 380 with crossglide Inserter is packed in individual sterile pouch. Each pouch contains one unit of Cu 380 along with crossglide Inserter (used for insertion purpose) and label insert. All the components are packed in Film/Film pouch. The pouch is then gamma sterilized and can be stored for up to one year.

Cu 380 IUD is inserted into the uterus by the physician/doctor. A plastic string tied to the end of the IUD hangs down through the cervix into the vagina which can be used to check/verify that the IUD is in place by feeling the string. The string is also used by physician/doctor to remove the IUD.

Crossglide Inserter (Accessory)

The crossglide IUD Inserter (CGI) is comprised of an everting Membrane (crossglide) that delivers a copper IUD into the uterine cavity in women who are seeking contraception. The crossglide Inserter is supplied by crossbay. Crossglide has a 4.5mm outer diameter when pressurized with an integral Inflation Tube and White Pinch Clamp with user-supplied 3cc syringe and saline. Upon pressurization, the CGI has 1 to 4 atmospheres of hydraulic pressure that delivers the IUD and Inner Catheter into the uterine cavity. The Inner Catheter has a distal lumen that can house an IUD in a loaded configuration and a Hub at the proximal end. Within the Inner Catheter is a Displacer with a lumen that contains the suture threads of the IUD. The Outer Tube contains markings and a blue Flange for providing an indicator of insertion depth. The CGI is packaged on a pouch card with a Protective Tube for crossglide and IUD with cut out tabs holding the Hub of the Inner Catheter and proximal end of the Displacer. The proximal ends of the

IUD sutures are threaded under and held by the blue Flange. The CGI with IUD and pouch card are sealed within a pouch and gamma sterilized.

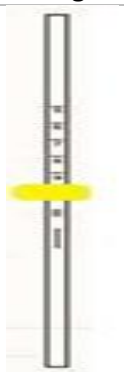


Cu 380/ Mini Cu 380 with crossglide Inserter

4.2 A reference to the previous generation(s) or variants if such exist, and a description of the differences

#	Variant Name	Variant Details
1.	Cu 380	Cu 380 with Loader, Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound
2.	Mini Cu 380	Mini Cu 380 with Loader, Mini Cu 380 with CrossGlide Inserter & Mini Cu 380 with Disposable Uterine Sound

4.3 Description of any accessories which are intended to be used in combination with the device

S.No	Accessory Name	Image	Intended purpose
1.	Insertion tube along with Flange		Insertion tube is used for loading and insertion of IUD through uterine cavity. Flange is used for adjusting the measured uterine depth on the insertion tube.
2.	Solid rod		Solid rod is used for pushing the loaded IUD to release the arm of the IUD in the uterine cavity.

4.4 Description of any other devices and products which are intended to be used in combination with the device

Intrauterine Contraceptive Device- Cu 380, Mini Cu 380 is not intended to be used in combination with the device.

5. Risks and warnings

5.1 Risk Estimations

As per Risk Management process, we estimated the risks for each hazardous situation. The risk estimation incorporates an analysis of the probability of the occurrence and level of severity to the end user. The possible consequences are listed for the use of risk evaluation and risk control.

Probability of Occurrence (per use):

Sales Data is considered for cumulative for all 02 variants

Year	Total	Complaints
2019-2020	23350	00
2020-2021	30750	00
2021-2022	29500	32
2022-2023	77320	91
2023-2024	109650	50*Complaints related to loader.
2024-2025	132500	19*Complaints related to loader.
Total	**403070**	**192**

Annual Average Sales = **403070**/6=67178

Annual Average Complaints = 192/6=32

Probability of improbable event occurrence = Annual avg. complaints / Annual avg sales

= 32/**403070**= 12,595

We have identified 5 probability levels from Improbable (O1) TO Frequent (O5). These probability levels are exponentiated by 0.5.

Definition	Probability	Description	Value
Improbable	<1/20000	This will probably never happen or recur	O1
Remote	< 1/2000	Do not expect it to happen or recur but it is possible it may do so	O2
Occasional	< 1/200	Might happen or recur occasionally	O3
Probable	< 1/20	Will probably happen or recur, but it is not a persisting issue / circumstance	O4
Frequent	$\geq$ 1/2	Will undoubtedly happen or recur, possibly frequently	O5

Severity:

When estimating the severity for harms of each hazardous situation, we have leveraged the objective evidence to support our estimates. Objective evidence include:

- Similar products performance

- Regulatory data (such as adverse events reported to FDA, MAUDE, MHRA database)
- Scientific white papers published in relation to the device and harms
- Applicable standards
- End-user expertise and feedback
- Pre-clinical test data

We have identified 5 severity levels from Catastrophic (S5) to Negligible (S1). The worst-case harm is "Uterus Perforation" are identified based on the harms that may result from Intrauterine Contraceptive Device- Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound. The further severity levels are estimated from the hazardous situation.

Rating	Definition	Harm	Value
Catastrophic	Results in life-threatening and/or reversible injury which require professional medical intervention	Uterus Perforation	S5
Critical	Results in prolonged discomfort which may lead to Major injury, which require professional medical intervention	Pelvic inflammatory Disease, ectopic pregnancy	S4
Serious	Minor Injury which require professional medical intervention	Menstrual cramps, Menstrual Bleeding, Ovarian cysts, misplacement of the device	S3
Minor	Temporary discomfort result which require professional medical intervention	Infection within the 3 weeks of IUD implantation, Irregular or heavy periods, spotting periods, expulsion, Allergic reactions, Bleeding, Unexpected Pregnancy, Difficulty in placing the IUD	S2
Negligible	Inconvenience & temporary discomfort does not require professional medical intervention	Pain, Itching, User inconvenience to perform implantation, Burning & Irritation, Lost Strings, Delay in procedure, Smelly discharge, Patient discomfort	S1

5.2 Residual risks and undesirable effect

5.2.1 Residual risks

#	Residual Risk	Total Hazards	Leading Hazardous Situation	Hazard ID Details	Status
1.	Uterus	04	• Improper IUD	D80, D87, D88,	Conditionally Accepted

#	Residual Risk	Total Hazards	Leading Hazardous Situation	Hazard ID Details	Status
	Perforation		implantation	D89	based on the RBA through Medical & Clinical Benefits
2.	Pelvic inflammatory Disease	14	• Inadequate pre-patient evaluation • Microbial Contamination • Contamination	D22, D43, D81, D82, D84, D86, D93, D100, D101, D102, D105, D106, D108, D110	Conditionally Accepted based on the RBA through Medical & Clinical Benefits
3.	Allergic reactions, Menstrual Bleeding Menstrual Cramps	13	• Misplacement of the device • Device Embedded in tissue • Inadequate pre-patient evaluation • Tissue Rupture	D90, D91, D92, D94, D96, D97, D98, D99, D103, D104, D107, D114, D115	Conditionally Accepted based on the RBA through Medical & Clinical Benefits
4.	Unwanted Pregnancy	09	• Product Structure deformity • Product degradation • Device Migration • Misplacement of IUD	D78, D79, D83, D85, D95, D109, D111, D112, D113	Conditionally Accepted based on the RBA through Medical & Clinical Benefits

5.2.2 Side effects

The following adverse side effects may occur when Intrauterine Contraceptive Device- Cu 380, Mini Cu 380 is used:

- IUD Expulsion
- Pain and excessive bleeding during periods
- Positive Pregnancy test
- Dislocation of IUD
- Migration of IUD
- Anemia
- Back ache
- Vaginal inflammation

- Pain during sex
- Uterine perforation

5.3 Warnings and precautions

Prior to use inspect the package for any visible damage or defect.

5.4 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

FSCA Related to – Intrauterine Contraceptive Device- Cu 380, Mini Cu 380

FSCA during the PSUR reporting period and the status of the FSCA

Type of action	Starting date	Status of the FSCA	Mnfr. Reference number	Rationale and description of action taken	Impacted regions
NA	NA	NA	NA	NA	NA

Actions are taken for safety reasons outside the FSCA

Type of action	Starting date	Status of the action	Rationale and description of action taken	Impacted regions
NA	NA	NA	NA	NA

6. Summary of clinical evaluation and post-market clinical follow-up (PMCF)

6.1 Summary of clinical data related to a similar device, if applicable

The Intrauterine Contraceptive Device - Cu 380, Mini Cu 380 belongs to the “Intrauterine Device” group. In the present market there are many similar devices and/or benchmark devices available with same intended purpose and are having the same generally acknowledged state-of-the-art.

These similar devices fall under “Well-Established Technology”. Data from similar devices is considered for the conformation of conformity to the Intrauterine Contraceptive Device - Cu 380, Mini Cu 380 relevant general safety and performance requirements. The similar device data is used to demonstrate ubiquity of design, lack of novelty, known safety and performance profile of a generic group of devices, etc.

The below mentioned similar devices data is used to evaluate the Intrauterine Contraceptive Device - Cu 380, Mini Cu 380 relevant general safety and performance requirements as part of literature review. These similar devices contain the same Raw materials and same intended purpose, but due to insufficient information availability the full assessment of equivalence is not possible. Therefore, these similar devices are used for the same clinical intended purposes as the Intrauterine Contraceptive Device - Cu 380, Mini Cu 380 and are considered to be similar but non-equivalent devices.

#	Device Name	Brand Name	Manufacturer Name & Country	Image	Intended use
1.	Intrauterine Contraceptive device	Nova T 380 Ag	Bayer Ag		Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound offer almost complete protection against pregnancy having shelf life 5 years and it remains effective for period of 5 years.

6.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Not Applicable

6.3 Summary of clinical data from other sources, if applicable

Not Applicable

6.4 An overall summary of the clinical performance and safety

The Intrauterine Contraceptive Device- Cu 380, Mini Cu 380 comply with all the Safety and Performance requirements with respect to the intended use of the device from the Clinical Evaluation study. The clinical evaluation is complete and conforms to the essential requirements. The Clinical evidence is

demonstrated with the relevant essential requirements as per Annex I of MDR. Risk Mitigation has been established as per the guidelines of EN ISO 14971:2019/A11:2021.

6.5 Ongoing or planned post-market clinical follow-up

Post market clinical follow-up activities for Intrauterine Contraceptive Device- Cu 380, Mini Cu 380 are ongoing from 2022-2027.
The study will be Single arm, Multicentric, open-label, observational, prospective clinical study

- Subjects will be fully explained about the study and signed informed consent will be taken. The subjects who met the inclusion criteria will be enrolled for the study.
- The rates of uterine perforation during insertion, the efficacy in preventing pregnancy and other complications related to IUD will be assessed through Case Report Forms.
- There will be six follow up visits after the insertion of IUD after one month, 1st year, 2nd year, 3rd year, 4th year and 5th year.
- During the follow up visit of one year, second year, third year, fourth year and fifth year the reversible fertility condition also will be verified in those subjects who had removed the IUD's during these years.
- At every follow up visit the Investigator will examine the subject and position of IUD and overall well-being of the subject. The investigator will be evaluating the subjects for the product performance, safety, benefits, risks, satisfaction, any side effects, and adverse device effect. The results will be update in the corresponding case report form.

Once all subjects complete the follow up visit, the final data analysis will be done and the outcome of each product will be reported in PMCF report. The Interim data analysis will be performed after every year and an interim report will be prepared based on the outcome.

7. Possible diagnostic or therapeutic alternatives

Other methods of contraception include:

- Oral contraceptives
- Condoms
- Progestin implants
- Progestin shots
- Vaginal rings
- Cervical caps
- Hormonal patches
- Diaphragms

- Sponges
- Abstinence
- Fertility awareness
- Permanent sterilization

8. Suggested profile and training for users

The device will be inserted by Trained Medical Professionals. Mandatory training is necessary to perform the procedure.

9. Reference to any harmonized standards and CS applied

9.1 List of Harmonized Standards

#	Standard ID	Current Issue	Title
1.	EN ISO 13485	2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
2.	EN ISO 14971	2019/A11:2021	Medical devices - Application of risk management to medical devices
3.	EN ISO 20417	2021	Information supplied by the Manufacture of Medical devices
4.	EN ISO 15223-1	2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
5.	EN 62366-1	2015+AC:2015+ AC:2016+A1:2020	Medical devices - Application of usability engineering to medical devices
6.	EN ISO 7439	2023	Copper-bearing contraceptive intrauterine devices — Requirements and tests
7.	EN ISO 10993-1	2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
8.	EN ISO 10993-3	2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
9.	EN ISO 10993-5	2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
10.	EN ISO 10993-10	2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
11.	EN ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests

			for systemic toxicity
12.	EN ISO 10993-12	2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
13.	EN ISO 11737-1	2018/A1:2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
14.	EN ISO 11737-2	2020	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
15.	EN ISO 11137-1	2015/A2:2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
16.	EN ISO 11137-2	2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose
17.	EN ISO 11607-1	2020	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
18.	EN ISO 11607-2	2020	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
19.	BS EN 556-1	2001/AC:2016	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Requirements for terminally sterilized medical devices.
20.	BS EN 556-2	2015	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" Requirements for aseptically processed medical devices

9.2 List of Other Applicable Standards

#	Standard ID	Current Issue	Title
1.	ISO 13485	2016	Medical devices - Quality management systems - Requirements for regulatory purposes
2.	ISO 14971	2019	Medical devices - Application of risk management to medical devices
3.	ISO 15223-1	2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
4.	ISO 14630	2012	Non-active surgical implants - General requirements
5.	IEC 62366-1	2015/AMD 1:2020	Medical devices – Part 1: Application of usability engineering to medical devices

6.	ASTM D4169-22	2022	Standard Practice for Performance Testing of Shipping Containers and Systems
7.	ISO 10993-1	2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
8.	ISO 10993-5	2009/AMD 1:2019	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
9.	ISO 10993-3	2014	Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
10.	ISO 10993-10	2021	Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
11.	ISO 10993-11	2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
12.	ISO 11737-1	2018/AMD 1: 2021	Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products
13.	ISO 11737-2	2019	Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
14.	ISO 11607-1	2019/CD AMD 1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
15.	ISO 11607-2	2019/CD AMD 1	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
16.	ISO 7439	2015	Copper-bearing contraceptive intrauterine devices — Requirements and tests
17.	ISO 14644-1	2015	Cleanrooms and associated controlled environments —Part 1: Classification of air cleanliness by particle concentration
18.	ISO 14155	2020	Clinical investigation of medical devices for human subjects - Good clinical practice
19.	ISO/TR 20416	2020	Medical devices — Post-market surveillance for manufacturers

9.3 Guidelines

#	Guideline	Current Issue	Title
1.	MEDDEV 2.7.1 Rev. 4	June 2016	Clinical evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC

2.	MEDDEV 2.5/5 Rev. 3	February 1998	Evaluation of clinical data: A guide for manufacturers and notified bodies
3.	MEDDEV 2.12-1 Rev. 8	January 2013	Vigilance system for medical devices
4.	MEDDEV 2.12/2 Rev. 2	January 2012	Post-market clinical follow-up studies: A guide for manufacturers and notified bodies
5.	NB-MED 2.12/Rec. 1	July 2019	Post Market surveillance
6.	MDCG 2021-24	Oct 2021	Guidance on classification of medical devices
7.	MDCG 2020-6	2020	Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC.
8.	MDCG 2018-1 Rev.4	April 2021	Guidance on BASIC UDI-DI and changes to UDI-DI
9.	MDCG 2020-7	April 2020	Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies
10.	MDCG 2020-8	April 2020	Post-market clinical follow-up (PMCF) Evaluation Report Template - A guide for manufacturers and notified bodies
11.	MDCG 2022-21	December 2022	Guidance On Periodic Safety Update Report (PSUR) According to Regulation (EU) 2017/745 (MDR
12.	MDR 2017/745 Annex XIV, Part A & B	August 2019	Medical Devices Regulation Annex XIV - Clinical evaluation and post-market clinical follow-up
13.	MDCG 2019-9 Rev.1	March 2022	Summary of safety and clinical performance A guide for manufacturers and notified bodies

9.4 Regulations

#	Regulation	Title
1.	EU MDR 2017 /745	European Union Medical Device Regulation

Summary of Safety and Clinical Performance Intended for Patient

Introduction

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions for Use to provide information on the safe use of the device.

1. Device identification and general information

1.1	Device trade name(s)	Intrauterine Contraceptive Device- Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound
		Brand Names: • Copper Y 380 • Copper Y Mini 380 • Yanae Cu 380 with CrossGlide Inserter • Copper Y Cu 380 with Loader • Yanae Mini Cu 380 with CrossGlide Inserter • Copper Y Mini Cu 380 with Loader • Cu 380 • Mini Cu 380
1.2	Manufacturer's name and address	PREGNA INTERNATIONAL LTD. Plot No. 219, Survey No. 168, Dabhel Co. Op. Ind. Soc. Ltd., Dabhel, Daman (U.T.)- 396210, India Phone : +(91)-(260)-3206372/3207093. Fax : +(91)-(22)-23513484. www.pregna.com
1.3	Basic UDI-DI	
i.	Cu 380	89040453pregnaCu3800000YA

ii.	Mini Cu 380	
1.4	Year when the device was first CE-marked	2006

2. Intended use of the Device

2.1 Intended Purpose

Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound provide very reliable protection against pregnancy for up to five years.

2.2 Indication(s) and target population(s)

Medical Indications: Intrauterine contraceptive devices are indicated for use in women of child bearing age. This is a reversible method of birth control, which means that a woman can become pregnant again after the device is removed.

Target Population: Women of child bearing age.

2.3 Contraindications and/or limitations

Contraindication (Absolute)

- Cancer of the uterus, cervix, or other parts of the female reproductive organs
- Unexplained vaginal bleeding
- If you are pregnant
- A history of pregnancy outside the womb (ectopic pregnancy) or have a higher risk of it
- Current infection in the reproductive organs (such as the uterus or fallopian tubes)
- A sexually transmitted infection (STI) within the past 12 months, except for conditions such as bacterial vaginitis, repeated herpes infection, or Hepatitis B
- Infection following an abortion within the last 3 months, or pelvic inflammatory disease (PID)
- Abnormal shape or structure of the uterus (from birth or developed later)
- Allergy to copper

Contraindication (Relative)

- Low blood count (anemia)
- Heart valve disease
- Blood clotting problems

- Use of anti-inflammatory medicines
- Wilson's disease (a condition where copper builds up in the body)
- Having several sexual partners

3. Device Description

3.1 Device description

Cu 380

The Cu 380 was first introduced by Schering AG in 2002 under the brand name Nova T Cu 380.

It is a type of intrauterine device (IUD) used for birth control. Cu 380 is a newer version of the widely used Cu T 380A IUD, but instead of a "T" shape, it has a flexible "Y" shape. This design makes it easier and less painful to insert and remove.

The copper used in the Cu 380 is the same as in other commonly used IUDs, and its quality has been approved by experts during the consultation process. The number "380" refers to the surface area of copper on the device.

The Cu 380 provides very reliable protection against pregnancy and remains effective for up to 5 years. It also has a shelf life of 5 years.

Mini Cu 380

The Copper Y Mini Cu 380 is a type of intrauterine device (IUD) used for birth control. It is similar to the commonly used Copper T Cu 380A IUD, but it has a smaller frame called a "Mini" frame.

The copper used in this device is the same high-quality copper used in other IUDs made by the company, and its quality has been approved by experts. The number "380" refers to the surface area of copper on the device.

The Mini Cu 380 has a frame made of polyethylene with barium sulphate, with a coil of copper wire wrapped around its vertical arm. A small string made of nylon or HDPE is attached to the bottom of the IUD. This string allows the user to check that the device is in place and also allows a doctor to remove it when needed.

Each Mini Cu 380 is individually packed in a sterile pouch, along with insertion components such as a tube, flange, and solid rod. The pouch is sterilized with gamma radiation and can be stored for up to five years.

The device must be inserted by a doctor. A plastic string attached to the IUD hangs down through the cervix into the vagina. The user can gently feel this string to check that the IUD is correctly positioned, and the doctor uses the string to remove the device when required.

Cu 380 and Mini Cu 380 with Loader

The Cu 380 and Mini Cu 380 IUDs with a Loader are birth control devices that were first introduced by Leiras Oy, Finland, and later by Schering AG.

These devices have a Y-shaped frame made of polyethylene with barium sulphate, and a coil of copper wire on the vertical arm. A small string made of nylon is attached to the bottom of the device. This string allows the user to check that the device is in place and allows a doctor to remove it when needed.

Each IUD with Loader comes individually packed in a sterile pouch or blister tray, along with the Loader assembly, which helps the doctor load and insert the device safely. The pouch or tray is sterilized using gamma radiation and can be stored for the duration of its shelf life.

The IUD must be inserted by a doctor. A small string attached to the IUD hangs down through the cervix into the vagina. The user can gently feel this string to make sure the IUD is still in place, and the doctor uses the string to remove the device when necessary.

Loader (Accessory)

The Loader is a small device that helps the doctor load the IUD into the insertion tube and place it safely into the uterus while keeping everything sterile.

The Loader is made of biocompatible plastic (ABS), which is safe to use in medical devices. This is the same material used in other IUDs made by the company, such as the Pregna Etherena T Cu 380A.

All IUDs with the Loader, along with labels and instructions, are sealed in sterile pouches and sterilized using gamma radiation to ensure they are safe to use.

YANAE Cu 380 with crossglide Inserter and YANAE Mini Cu 380 with crossglide Inserter

The Cu 380 and Mini Cu 380 IUDs with CrossGlide Inserter are birth control devices used to prevent pregnancy.

The devices have a Y-shaped frame made of polyethylene with barium sulphate, and a coil of copper wire on the vertical arm. A small nylon string is attached to the bottom of the device. This string allows the user to check that the IUD is in place and allows a doctor to remove it when needed.

Each IUD with the CrossGlide Inserter comes individually packed in a sterile pouch, along with the Inserter (used by the doctor to place the device) and the label insert. The pouch is sterilized using gamma radiation and can be stored for up to one year.

The IUD must be inserted by a doctor. A small string attached to the IUD hangs down through the cervix into the vagina. The user can gently feel this string to verify that the IUD is in place, and the doctor uses the string to remove the device when necessary.

Crossglide Inserter (Accessory)

The CrossGlide Inserter (CGI) is a medical tool used by doctors to insert the copper intrauterine device (IUD) into the uterus in women who wish to prevent pregnancy.

The inserter uses a special soft everting membrane (CrossGlide) that gently places the IUD inside the uterus. The system helps make the insertion process smoother and more comfortable for the patient.

The CrossGlide Inserter has a small outer tube about 4.5 mm wide. It is used together with a small syringe containing saline (salt water) to create gentle hydraulic pressure that helps deliver the IUD into the uterus.

The inserter has:

- An Inner Catheter, which holds the IUD before it is released into the uterus.
- A Displacer, which guides the IUD and keeps the threads in place.
- An Outer Tube with depth markings and a blue flange, which helps the doctor position the device correctly.

The CrossGlide Inserter and the IUD are packaged together in a sterile pouch. Each pouch contains all necessary components and is sterilized using gamma radiation to ensure safety before use.

3.2 Materials that come in contact with patient

Device Trade Name	Material that comes in contact with patient
Cu 380, Mini Cu 380, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter	- T frame - Copper wire - Suture thread - Insertion tube - Flange - Solid rod
Cu 380 with Loader and Mini Cu 380 with Loader	- T frame

	- Copper wire - Suture thread - Insertion tube - Flange - Solid rod - Safeload
Cu 380 with Disposable Uterine Sound and Mini Cu 380 with Disposable Uterine Sound	- T frame - Copper wire - Suture thread - Insertion tube - Flange - Disposable Uterine Sound - Loader - Knob - Upper Grip/Top Grip - Bottom Grip - Aligner - Tyvek Tray (OHSL Pack)

3.3 Information about medicinal substances in the device, if any

Intrauterine Contraceptive Device- Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound contain **copper** as part of their structure. Copper is the active material that prevents pregnancy. It is slowly released in very small amounts into the uterus, where it changes the environment to stop sperm from fertilizing an egg.

Copper is not a drug on its own in this device, but it is considered an “ancillary medicinal substance” — meaning it supports the main function of the device (contraception) by providing a local chemical effect inside the uterus.

3.4 Description of how the device is achieving its intended mode of action

Intrauterine contraceptive devices prevent pregnancy mainly by stopping sperm from reaching and fertilizing an egg.

The copper on the device slowly releases small amounts of copper ions inside the uterus. These ions make it harder for sperm to move and survive, which prevents fertilization.

The presence of the IUD also causes natural changes in the lining of the uterus, making it difficult for a fertilized egg to attach and grow.

Once placed inside the uterus, the IUD provides effective protection against pregnancy for up to five years. If continued protection is needed after this time, a new IUD can be inserted immediately after removing the old one.

The IUD does not contain hormones, so it does not affect breastfeeding and does not interfere with normal sexual activity. It also does not require any daily action from the user.

This is a reversible form of contraception, fertility returns to normal once the device is removed.

3.5 Description of accessories, if any

S.No	Accessory Name	Image	Intended purpose
1.	Insertion tube along with Flange		The insertion tube is a small, thin tube used by the doctor to place the intrauterine device (IUD) gently into the uterus. The flange is a small adjustable part on the insertion tube that helps the doctor set the correct depth for placing the IUD safely and accurately inside the uterus.
2.	Solid rod		The solid rod is a small part of the insertion system used by the doctor to gently push the IUD out of the insertion tube and release it into the correct position inside the uterus.

4. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.1 How potential risks have been controlled or managed

To make sure the Cu 380 and Mini Cu 380 intrauterine devices (including all versions with Loader, CrossGlide Inserter, and Disposable Uterine Sound) are safe to use, the manufacturer follows a strict quality management system based on international medical device standards (ISO 13485:2016).

All possible risks related to the design, materials, and use of the device have been carefully identified, evaluated, and controlled through a detailed risk management process.

The following main steps are taken to manage risks:

- Designing and manufacturing the device to be as safe as possible.
- Adding protective measures in the device and during production to reduce risks.
- Providing clear safety information and instructions to doctors and users.

After applying these controls and verifying their effectiveness, the remaining (residual) risks are very low and are considered acceptable when compared to the proven benefits of the device in preventing pregnancy.

A detailed benefit–risk analysis has been performed using medical data, published studies, and information from similar devices already in use. The analysis shows that the benefits of using the device clearly outweigh the potential risks when it is used as intended by trained healthcare professionals.

Any remaining risks are clearly described in the product labelling and Instructions for Use (IFU) so that both doctors and users are aware of them and can take proper precautions.

4.2 Residual Risks

Although the Cu 380 and Mini Cu 380 intrauterine devices (IUDs) are carefully designed and tested for safety, a few rare risks may still occur even when the device is used correctly by a trained healthcare professional. These include:

- **Uterine perforation:** In very rare cases, the IUD may accidentally pass through or make a small hole in the wall of the uterus during insertion. This is a rare complication and is usually recognized and treated by the doctor immediately.
- **Pelvic inflammatory disease (PID):** There is a small chance of developing an infection in the pelvic area, usually within the first few weeks after insertion. Proper medical screening before insertion and good hygiene practices reduce this risk.
- **Allergic reaction or menstrual changes:** Some women may experience mild allergic reactions to copper, heavier menstrual bleeding, or stronger menstrual cramps, especially in the first few months after insertion. These effects often lessen over time.
- **Unintended pregnancy:** Although the device is very effective, no contraceptive method is 100% reliable. In rare cases, pregnancy may still occur.

4.3 Side effects

When using the Cu 380 or Mini Cu 380 intrauterine device (IUD), some women may experience side effects. Most of these are mild and improve with time, but in rare cases, they may require medical attention.

The possible side effects include:

- **IUD expulsion:** The IUD may come out of the uterus on its own, partly or completely. If this happens, it may no longer provide protection against pregnancy.
- **Pain or heavy bleeding during periods:** Some women may have stronger cramps or heavier bleeding, especially in the first few months after insertion.
- **Positive pregnancy test:** Although very effective, no contraceptive method is 100% reliable, and pregnancy can rarely occur.
- **Dislocation or movement of the IUD:** The IUD may slightly change its position inside the uterus. Your doctor can check and correct this if needed.
- **Migration of the IUD:** In very rare cases, the IUD can move from its original place and may need to be removed by a doctor.
- **Anemia:** Heavier bleeding may sometimes lead to low iron levels in the blood (anemia).
- **Backache:** Some users may experience mild back pain after insertion.
- **Vaginal inflammation:** Mild irritation or infection in the vaginal area can occur and should be treated by a doctor if symptoms persist.
- **Pain during sex:** Some women may feel discomfort during sexual intercourse.
- **Uterine perforation:** In extremely rare cases, the IUD may create a small hole in the wall of the uterus during insertion. This is usually identified and treated by the doctor.

4.4 Warnings and Precautions

Prior to use inspect the package for any visible damage or defect.

4.5 Summary of any field safety corrective action, (FSCA including FSN) if applicable

For the Intrauterine Contraceptive Device- Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Soundno serious safety issues or incidents have been reported that caused death or serious harm to patients, users, or others.

Because no such cases have been identified, no Field Safety Corrective Actions (FSCA) or Field Safety Notices (FSN) have been required or issued for these devices.

This means that, based on the available data and post-market monitoring, the devices have shown a good safety record in actual use.

5. Summary of clinical evaluation and post-market clinical follow-up

5.1 Clinical background of the device

The Intrauterine Contraceptive Device- Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound is a long-acting, reversible, and hormone-free contraceptive device. It has been designed and manufactured in accordance with international and regulatory standards to ensure safety, quality, and effectiveness.

The device and its accessories are developed and tested in compliance with the following standards and specifications:

- EN ISO 7439:2015 / ISO 7439:2015 – Copper-bearing intrauterine contraceptive devices – Requirements, tests, and guidance on clinical investigations.
- WHO/UNFPA Technical Specification (2016) – Technical and performance specifications for IUDs.
- EN ISO 14971:2019/A11:2021 – Risk management for medical devices, ensuring that all known and foreseeable risks are identified and minimized.
- EN ISO 13485:2016/A11:2021 – Quality management systems for medical devices, ensuring the device is produced under controlled manufacturing conditions by trained personnel.

The performance of the Cu 380 and Mini Cu 380 IUDs meets the clinical and safety requirements necessary for their intended use — prevention of unintended pregnancy for up to 5 years.

All foreseeable hazards have been identified, and appropriate risk control measures have been implemented to ensure the device is safe and effective when used as intended.

5.2 The clinical evidence for the CE-marking

Intrauterine Contraceptive Device- Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine are already approved and certified for use in Europe as medical devices under the EU Medical Device Directive (MDD 93/42/EEC).

Because these devices have been previously CE-marked, they are considered “legacy devices” under the current EU Medical Device Regulation (MDR 2017/745).

Clinical evidence and safety data from these CE-marked devices show that the Cu 380 and Mini Cu 380 IUDs:

- Effectively prevent pregnancy when used as intended.
- Have a well-established safety profile, with rare complications.
- Meet all clinical requirements as outlined in current EU regulations for devices that were CE-marked under older directives.

This means that the devices have a long history of safe and effective use, which supports their continued approval and use in women seeking reversible, hormone-free contraception.

Device Name:	Intrauterine contraceptive device
Models/Variants:	Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound
93/42/EEC (MDD) Cert. No.:	11233-2017-CE-IND-NA-PS Rev 7.0
Notified Body Details:	DNV Product Assurance AS, Veritasveien 3, 1363 Høvik, Norway

Similar Device Details:

The Intrauterine Contraceptive Device- Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound belong to the "intrauterine device" group of contraceptives.

There are many similar IUDs available on the market with the same purpose — preventing pregnancy in women. These devices use well-established designs and materials and follow the current state-of-the-art standards for safety and performance.

This means that the Cu 380 and Mini Cu 380 IUDs are part of a recognized group of safe and effective devices that are widely used around the world.

#	Device Name	Brand Name	Manufacturer Name & Country
1.	Intrauterine Contraceptive Device	Nova T 380 Ag	Bayer Ag

5.3 Safety

The Intrauterine Contraceptive Device- Cu 380 & Mini Cu 380, Cu 380 with Loader and Mini Cu 380 with Loader, Cu 380 with CrossGlide Inserter and Mini Cu 380 with CrossGlide Inserter, Cu 380 with Disposable Uterine Sound & Mini Cu 380 with Disposable Uterine Sound have been carefully evaluated for safety and effectiveness**.**

All potential risks that may remain after proper use (residual risks) have been assessed. The available medical evidence and published studies show that the benefits of using these devices — preventing unintended pregnancy — clearly outweigh the small remaining risks**.**

Any remaining risks are considered acceptable when the device is used as intended, and all important safety information is provided to the user through the product label and Instructions for Use**.**

This means that, when used correctly under medical supervision, the devices are safe and effective for contraception.

Residual risks	Medical Benefits
1. Uterus Perforation 2. Pelvic inflammatory Disease 3. Allergic reactions, Menstrual Bleeding,	Benefit related to Legacy Device: 1. Intrauterine contraception in women is safe, effective method when compared to other existing methods. 2. It can be used as emergency contraception device. 3. No unwanted pregnancy or ectopic pregnancy is

Menstrual Cramps 4. Unwanted pregnancy	identified. 4. Less infection rates. Benefit related to Similar Device: 1. Low perforation rates. 2. Lower expulsion rates. 3. Low risk of developing Pelvic inflammatory disease. 4. Reduced bleeding. 5. IUD easier to insert and causes less pain at insertion. 6. Reduced or no pain complaints. 7. Moderate pelvic pain is observed. 8. Reduced dysmenorrhea and menstrual blood loss. 9. Provide the highest contraceptive efficacy and rates of satisfaction. 10. No IUD-related artifacts were found.

As part of our commitment to safety, the Intrauterine Contraceptive Device (IUD) are monitored even after they are placed on the market. This is done through a Post-Market Clinical Follow-up (PMCF) program, which is part of our quality system.

The purpose of this follow-up is to:

- Collect feedback from users and healthcare professionals about the safety and performance of the IUD.
- Confirm that the device continues to work effectively and safely throughout its expected lifetime.
- Identify and assess any remaining risks or new risks that may emerge over time.

The PMCF process uses systematic surveys and data collection to ensure that any issues are detected and addressed quickly.

Post market clinical follow-up activities for Intrauterine Contraceptive Device- Cu 380, Mini Cu 380 are ongoing from 2022-2027.

6. Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

7. Suggested training for users

The device will be inserted by Trained Medical Professionals. Mandatory training is necessary to perform the procedure.

Revision history

Rev #	Date	Initiated By	Summary of Change (Amended / Updated)
00	*14.09.2022*	*Mr. Ranjit Gaikwad*	*Initial Release*
01	*20.08.2025*	*Mr. Ranjit Gaikwad*	*Added Summary of safety and clinical performance intended for patient*
02	*13.10.2025*	*Mr. Ranjit Gaikwad*	*Summary of Safety and performance intended for patient is written in layman, easily understandable language, avoiding medical jargon*