SMB®

TCu 380Ag Normal & Mini

INTRAUTERINE CONTRACEPTIVE DEVICE

SiLVEE
FLY TO SAFETY AND COMFORT

The n☆ Touch Technology

SINGLE HANDED INSERTER

IUD - TCu 380Ag Normal - Patented
Haptic - Based IUD Inserter - Patent Pending

CE
In Progress

TCu 380Ag Normal & Mini with No Touch Technique (Single Handed)

IUDs do not protect against sexually transmitted diseases / AIDS

LEAFLET INTENDED FOR THE HEALTHCARE PROFESSIONAL

SMB TCu 380Ag should be inserted and removed only by / under the supervision / training of a gynaecologist/physician.

DESCRIPTION

TCu380Ag Intrauterine device is ready-to-use in a sterile package and is composed of Y shaped two flexible arms and vertical stem made of low density polyethylene with barium sulphate, opaque to X-rays. It is wound with 0.40mm diameter copper - silver alloy wire providing a surface area of 380mm^2 ± 10%. The frame is tied with Polyamide Monofilament thread for easy removal and is supplied preassembled in a no-touch inserter system comprising an insertion tube, rod, handle and slider mechanism. The complete assembly is sterile packed in a peelable blister pouch. The insertion tube is equipped with a movable flange to aid in gauging the depth to which the insertion tube should be inserted through the cervical canal and into the uterine cavity. (FIGURE I)

The Copper-Silver alloy wire delays the fragmentation of the wire and prolongs the life span of the device.

The single unit pouch a containing TCu380Ag IUD with its insertion components is a sterile medical contraceptive device for Single Use Only.

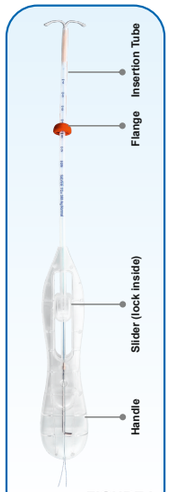


FIGURE I

Overall Qualitative & Quantitative information on the Material

Component	Composition	Approximate weight
Cu-Ag Wire	99.99% OFE, (Cu 90%+Ag10%)	Mini: 325-355 mg Normal: 335-365 mg
Y Frame	Compound of LDPE+BaSO4	Mini: 150 mg Normal: 200 mg
Monofilament	Polyamide	

INDICATIONS

Intrauterine Contraception in women of child bearing age

Intended Use:

The TCu380Ag IUD, is indicated for intrauterine contraception in women of child bearing age.

- TCu380Ag can be inserted after a birth or abortion.
- TCu380Ag can be used as emergency contraception.

Clinical Benefit :

- IUD TCu380Ag is extremely effective in preventive pregnancy
- It is a reversible method of contraception
- No maintenance is required

TCu380Ag is recommended for women who :

- Women of child bearing age
- Are in mutually monogamous relationships
- Have no history of pelvic inflammatory disease (PID)
- Choose not to use hormonal contraceptives

TCu380Ag should not be inserted in a woman who :

- Is pregnant

- Still retains a previously inserted IUD
- known or suspected malignancy of the genital tract, including undiagnosed vaginal bleeding and an unresolved abnormal Pap smear, or a severe uterine abnormality.
- Had a postpartum endometritis or postabortion infection in the past three months
- Has Wilson's disease or a known allergy to copper
- Has genital actinomycosis

TCu380Ag should not be the method of first choice for a woman who has :

- Painful or long menstrual periods
- Severe anemia
- Cervical stenosis or narrowing of the cervical canal
- No access to a health center for follow-up care
- A history of ectopic pregnancy

Indicative selection criteria of the Models Mini, Normal

Size	Vertical Arm Length	Horizontal Width	Uterine Cavity Size	Approx. Sound Measuring Range
Mini	30.5 mm	24 mm	36 mm	6-7.5 cm
Normal	33 mm	31 mm	45 mm	7-8.5 cm

The above information is indicative only. The final decision of selection of the correct model for the patient is to be made by the Healthcare Professional.

Instruction for healthcare provider to assess the client for suitability to receive a Copper bearing IUD by:

- Undertaking an assessment of medical eligibility criteria to rule out contraindication;
- Rule out pregnancy using the pregnancy checklist;
- Assessment of STI risk including HIV

STERILIZATION METHOD AND USE:

TCu380Ag IUD is sterilized by Gamma Radiation. The Sterile single unit pouch containing TCu380Ag IUD with its insertion components are **"For single use only".**
Do not re-sterilize.

CONTRACEPTIVE LIFE:

TCu380Ag can remain inserted in the uterus for a maximum lifetime of 5 years. If continued contraception is desired by the patient, a new TCu380Ag should be inserted at once.

INSERTION PERIOD

TCu380Ag IUD may be inserted at any time during the menstrual cycle, provided that the woman is not pregnant and has been consistently using an effective contraceptive method since her last menstrual period.

Many clinicians prefer to insert the IUD within seven days of the onset of menstruation, as the cervical os may be slightly dilated during this time, which can facilitate insertion, reduce discomfort, and make pregnancy highly unlikely. However, insertion during menstruation is not mandatory, and the device may be inserted at other times in the menstrual cycle when pregnancy can be reasonably excluded.

For emergency contraception, the TCu380Ag IUD may be inserted within 5 days (120 hours) after unprotected coitus, provided pregnancy has not occurred.

A woman can have a copper-bearing IUD inserted up to 48 hours after delivery, including immediately after delivery of the placenta. If the delivery is by caesarean section, a copper-bearing IUD can be placed after delivery of the placenta, before closing the uterus. If the copper-bearing IUD is not inserted within 48 hours after delivery, then a woman can have the IUD inserted at four weeks postpartum or thereafter, if it can be determined that the woman is not pregnant. In order to minimise the risk of uterine perforation, expulsion, and insertion-related complications during the period of uterine involution, It is recommended that the device be inserted not earlier than 6 weeks postpartum or post-abortion, after uterine involution is complete. If uterine involution is substantially delayed, insertion may be considered up to 12 weeks postpartum or post-abortion, based on clinical assessment.

RECOMMENDED INSERTION TECHNIQUE

Insertion must absolutely be carried out by a qualified Healthcare Professional equipped with the appropriate instruments under aseptic conditions. It is imperative that a no-touch technique is employed throughout the insertion procedure to ensure sterile handling.

The inner packaging of the IUD must not have been opened or damaged. Insertion must not be carried out if the IUD or its accessories are damaged or insert before date has passed.

A. PREPARATION

1. Perform a careful bimanual examination to determine the version, flexion and uterine axis.
2. Insert a vaginal speculum to expose the cervix. Cleanse the cervix and vaginal walls with sterile cotton wool dipped in antiseptic solution, Wipe all secretion away from the external os.
3. Grasp the anterior lip of the cervix with a single-tooth tenaculum, taking a good bite through the cervical lip so that steady downward traction to straighten the uterine axis can be maintained without risk of cervical laceration.
   Reflex contraction, which causes cramp of the uterus when the tenaculum is applied, can be prevented by injection of a local anaesthetic into the anterior lip or a paracervical block.
4. Carefully sound the uterus to determine its depth and to confirm the direction of its axis. If the sound meets more than normal resistance at the internal os, it may be advisable to gently dilate the cervical canal to 4-5 mm, using sterile, tapered rather than cylindrical dilators. In the absence of other instruments for measurement of the internal dimensions of the uterine cavity, the sound may be used to obtain an idea of its configuration.
   The IUD should be loaded in to the insertion tube not more than five minutes before insertion.

REUSE

The IUD, its accessories and the hysterometer must not be reused. In case of reuse, the patient is exposed to multiple risks of infection and the IUD loses its claimed performance.

B. PROCEDURE FOR LOADING

As a general principle, TCu380Ag should be inserted under aseptic conditions using sterile gloves. The following steps should be followed when inserting TCu380Ag :

Step 1 — Open Sterile Package

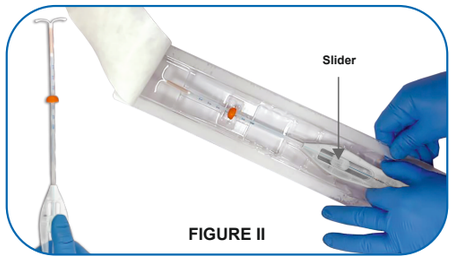


FIGURE II

- Open package aseptically and Remove inserter while maintaining sterility.
- Pick up the handle of the inserter containing the TCu380Ag IUD and carefully release the threads so that they hang freely. (FIGURE II)

Step 2 — Load the Device

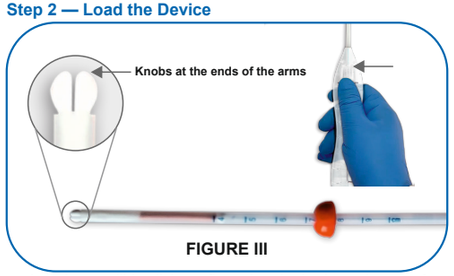


FIGURE III

- A distinct audible click confirms that the horizontal arms of the IUD are securely locked inside the insertion tube, indicating proper engagement of the loading mechanism. (FIGURE III)

Note : Loading the IUD into the insertion tube is an irreversible process. Once the IUD is released from or withdrawn out of the insertion tube, it cannot be reloaded into the tube because of the locking mechanism of the holder.Therefore, avoid pulling the slider back prematurely before the intended insertion step.

Step 3 — Set the Flange

Using the uterine sounding depth measured with a hysterometer, adjust the flange position on centimeter scale on the insertion tube so that it corresponds to the uterine depth. (FIGURE IV)

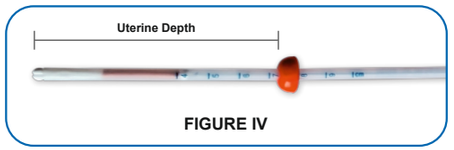


FIGURE IV

Step 4 — Insert through Cervix

- Advance inserter gently through the cervical canal
- Hold when the flange is about 1.5–2 cm from the external cervical os. At this stage the IUD will be half way in the Uterine cavity. (FIGURE V)



FIGURE V

Step 5 — Open the Arms

Pull the slider back to the marked line. Pulling the slider till marked line will fully deploy the arms of IUD in Uterine cavity. (FIGURE VI)


FIGURE VI

Step 6 — Advance to fundus

Now Gently advance inserter until flange touches the cervix. This will ensure the IUDs placement at the uterine fundus. (FIGURE VII)



FIGURE VII

Step 7 — Release the IUD

A distinct audible click indicates the release of the IUD from the loading mechanism. (FIGURE VIII)



FIGURE VIII

Step 8 — Withdraw Inserter

Now Withdraw inserter carefully while keeping slider fully down.

Step 9 — Cutting of Threads

Cut the threads so that they protrude only 2-3 cm from the cervix.

If you suspect that TCu380Ag IUD is not in the correct position, check placement (with ultrasound, if necessary), If it is not positoned completely within the uterus, remove it and replace it with a new TCu380Ag IUD. Do not reinsert an expelled or partially expelled IUD.

REMOVAL TECHNIQUE

Removal can take place whenever the user would like to become pregnant or whenever the user would like to switch to another type of contraception or at the time of replacement.

Hold the threads with forceps as close as possible to the external orifice of the cervix and apply steady force. Applying unsteady force/ pressure may cause breakage of arm.

Regular traction of the threads along with traction towards the bottom with the Pozzi forceps make it possible to remove the IUD without difficulty.

If the threads are not visible and the device is in the uterine cavity, removal should be postponed until after the next menstrual bleeding since the threads usually become visible immediately after menstruation. If they are still not visible, the device may be removed using a narrow tenaculum. This may require dilatation of the cervical canal.

SMB TCu380Ag should be removed after five years. If the woman wishes to continue using the method, a new device can be inserted at the same time.

If pregnancy is not desired, the removal should be carried out during menstruation. If the device is removed mid-cycle and the woman has had intercourse within a week, she is at risk of pregnancy unless a new device is inserted immediately following removal.

Insertion and removal may be associated with some pain and bleeding. The procedure may precipitate fainting as a vasovagal reaction, and a seizure in an epileptic patient.

If it is very difficult, removal under general anaesthesia should be considered as per the most appropriate method.

CONTRAINDICATIONS

A. ABSOLUTE

- Pregnancy
- Acute pelvic inflammatory disease or a history of pelvic inflammatory disease (PID)
- Postpartum endometritis or abortion
- Sexually transmitted diseases (STD) including a lower genital tract infection, such as gonorrhea or Chlamydia
- At high risk of STDs because she or her partner has multiple sexual partners
- known or suspected malignancy of the genital tract, including undiagnosed vaginal bleeding and an unresolved abnormal Pap smear, or a severe uterine abnormality
- Congenital uterine abnormality
- Allergy to Copper
- Untreated acute cervicitis or vaginitis including bacterial vaginosis, until infection is controlled
- Conditions associated with increased susceptibility to infections with microorganisms. Such conditions include, but are not limited to leukemia, acquired immune deficiency syndrome (AIDS), and intravenous drug abuse
- Wilson's disease
- Small uterine cavity
- To avoid burning/perforation, radiotherapy and diathermy should be contraindicated, especially if applied to the lower pelvic region
- Patients with uterine fibroids

B. RELATIVE

- Severe Dysmenorrhea
- Disorders of blood coagulation
- Vascular Cardiac disease

WARNINGS

Ectopic Pregnancy

If a woman gets pregnant with IUD in place, there is a chance of having an extra-uterine pregnancy (a fertilized egg not implanting in the womb, but for instance in a fallopian tube) which should be evaluated.

Pelvic Infection

Although pelvic inflammatory disease(PID) in woman using IUDs is uncommon, IUDs may be associated with an increased relative risk of PID compared to other forms of contraception and to no contraception. The highest incidence of PID occurs

within 20 days after insertion. It is therefore, important to promptly assess and treat any woman who develop signs or symptoms of PID.

PID may lead to infertility. If the acute infection does not respond to treatment within a few days or if the woman requires hospitalization and / or antibiotic therapy, removal of the IUD should be considered.

Expulsion

Sometimes an IUD is pushed out of the womb into the vagina during the heavy flow of menses as womb remains slightly open during the menstrual period. If unnoticed, an unintended pregnancy could occur.

Breastfeeding

The use of a copper-containing IUD does not lead to a significant increase in the copper transport protein (ceruloplasmin) in the mother's blood or in the copper concentration of the breast milk. It has no effect on the composition of the breast milk or the child's growth.

However, the use of an IUD in breastfeeding women significantly increases the risk of uterine perforation (see below). A decision must be made whether to use or abstain from the use of TCu380Ag taking into account the benefit of breastfeeding for the child and the risk of uterine perforation for the mother.

Perforation

Partial or complete perforation or penetration of the uterine wall or cervix may rarely occur during insertion and may not be detected until a later time. Spontaneous migration has also been reported. The risk of perforation may be increased in women with abnormal uterine anatomy, fixed retroverted uteri or in breastfeeding women.

If perforation occurs, pregnancy may result and the TCu380Ag IUD must be located and removed. Delayed detection can lead to migration of the device outside the uterine cavity, adhesions, peritonitis, intestinal perforation or obstruction, abscess formation, and erosion of adjacent viscera.

Breast feeding at the time of the insertion and insertion up to 36 weeks after giving birth have been associated with an increased risk of perforation (see Table 1).

Table 1: Incident of perforation per 1000 insertions for the entire study cohort, stratified by breast-feeding and time since delivery at insertion (parous women).

	Breastfeeding at time of insertion	Not breastfeeding at time of insertion
Insertions≤ 36 weeks after delivery	5.6 (95% CI 3.9-7.9; n=6047 insertions)	1.7 (95%CI 0.8-3.1; n=5927 insertions)
Insertion> 36 weeks after delivery	1.6 (95% CI 0.0-9.1; n=608 insertions)	0.7 (95% CI 0.5-1.1; n=41910 insertions)

(Heinemann et al. 2015)

NSAIDS

Non-steroidal anti-inflammatory drugs (NSAIDs), including acetylsalicylic acid, naproxen, and ibuprofen, may be used for the management of pain or bleeding associated with IUD use and do not reduce contraceptive efficacy. Routine administration of prophylactic antibiotics at the time of IUD insertion is not recommended for women at low risk of sexually transmitted infections.

SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

SSCP will be available in the European database on Medical Devices once the URL to the Eudamed public Website http://ec.europa.eu/tools/eudamed is functional

INTERACTION WITH MRI, ELECTROTHERAPY, AND RADIOTHERAPY

Based on published literature, magnetic resonance imaging (MRI) examinations up to 1.5 Tesla in women with a copper intrauterine device (IUD) in situ do not result in displacement, heating, or functional impairment of the device and do not affect its contraceptive efficacy.

This is due to the non-ferromagnetic properties of copper, which prevent magnetic attraction or torque during MRI procedures. The presence of a copper IUD does not significantly affect MRI diagnostic image quality, although minor local artefacts may occur.

Electrotherapy using high-frequency current (e.g. diathermy or short-wave therapy) is contraindicated, particularly when applied to the lower pelvic region, due to the risk of conductive heating associated with metallic implants.

When metallic implants are present within the radiotherapy field, clinicians should carefully assess their impact on treatment, as metallic implants may alter radiation dose distribution.

PREGNANCIES DURING IUD USE

If women have a delayed period for 10 days and have symptoms of pregnancy such as nausea, tender breasts etc., they should be immediately directed to the clinic. When a pregnancy is confirmed, the IUD must be removed as soon as possible, without an invasive procedure. A pregnancy that continues with an IUD in place is subject to complications (miscarriage, spontaneous abortion, septic abortion).

PRECAUTIONS FOR USE

The device contains Cu as an ED substance and Phthalate in the PVCflange of the insertion tube. The device shall not be used if the patient is allergic to any of these substances.

Intrauterine devices must be used with caution in users receiving anticoagulant treatment or with a coagulation disorder.

Signs of movement or even expulsion of the IUD have been reported in women with a menstrual cup, but there is no certainty as to the link between the cups and the reported incidents. The possibility of a suction effect on the IUD when the menstrual cup is withdrawn has been suggested.

An IUD should be tolerated well after two cycles. If this is not the case, the persistence of bleeding and/or pain are reasons to consider removing the IUD.

It is recommended that the user seen again after the menstrual period following insertion, and then on a regular basis.

In case of suspected perforation during insertion, remove the IUD immediately. Perforation may also be detected later. If this happens, the IUD should be located and its removal considered.

If the retrieval threads are not visible at the cervix on follow-up examinations, pregnancy must be excluded. The threads may have been drawn up into the uterus or cervical canal and may reappear during the next menstrual period. If pregnancy has been excluded, the threads may usually be located by gently probing with a suitable instrument. If they cannot be found, the device may have been expelled. Ultrasound diagnosis may be used to ascertain the position of the IUD. If ultrasound is not available or unsuccessful, X-ray may be used to locate TCu380Ag IUD.

In case the device can not be located the device may have been expelled and implantation of another IUD or alternative contraception method should be considered.

INFORMATION TO BE GIVEN TO THE USER BY THE HEALTHCARE PROFESSIONAL

The Healthcare provider shall discuss suitability for use by most women and common misunderstandings about IUDs.

The healthcare provider must inform the contraceptive effectiveness, side effects, health benefit, health risk and complication associated with TCu380Ag to the user.

It is especially important that the users are able to recognise the onset of a complication as quickly as possible.

Users must learn to feel the threads to make sure that the IUD has not been expelled.

Table: Cumulative discontinuation rates (Kaplan-Meier estimates) per 100 users and Cla by type of termination

Type	First year		Second year		Third year		Fourth year		Fifth year	
	Rate	CI	Rate	CI	Rate	CI	Rate	CI	Rate	CI
Pregnancy	0.5	0.0–1.3	0.9	0.0–1.8	1.5	0.2–2.9	1.9	0.4–3.5	1.9	0.4–3.5
Expulsion	1.3	0.2–2.4	3.1	1.3–4.9	3.8	1.7–5.8	4.1	2.0–6.3	4.1	2.0–6.3
Bleeding problems	4.4	2.3–6.4	8.5	5.6–11.3	9.7	6.6–12.8	11.1	7.8–14.4	14.0	10.1–17.8
Pain	1.3	0.2–2.5	2.0	0.5–3.4	2.3	0.7–3.9	4.2	1.9–6.5	4.2	1.9–6.5
Perforation	0.3	0.0–0.8	0.3	0.0–0.8	0.3	0.0–0.8	0.3	0.0–0.8	0.3	0.0–0.8
Other medical reason	1.4	0.2–2.5	3.5	1.5–5.4	4.8	2.5–7.1	5.6	3.1–8.	1 6.4	3.7–9.2
Planning pregnancy	0.8	0.0–1.8	5.8	3.3–8.3	9.8	6.5–13.0	12.2	8.6–15.8	13.5	9.6–17.3
Other personal reason	2.4	0.8–3.9	4.5	2.3–6.6	6.5	3.8–9.1	8.7	5.6–11.8	11.9	8.2–15.6
Other reason	0.0	NA	0.0	NA	0.7	0.0–1.7	2.3	0.5–4.1	4.8	2.0–7.5
Overall discontinuation	11.8	8.6–14.9	25.3	21.0–29.5	33.5	28.9–38.1	41.0 3	6.2–45.8	47.5	42.6–52.4

[a] *95% confidence interval.*

Reference -Five-year clinical experiences with NOVA T®380 copper IUD, Bata´r et al., Contraception 66 (2002) 309–314

ADVERSE REACTIONS

The following adverse reactions and side effects have been reported with IUDs, and may occur after the IUD is inserted. Visit your doctor for any of the following reasons:

- Pregnancy with the IUD in the uterus or when it has been partially or completely expelled
- Partial or complete expulsion of the IUD
- Uterine puncture
- Bleeding or spotting between menstrual periods
- Missed or delayed menstrual periods
- Heavy or prolonged menstrual periods
- Painful menstrual periods
- Anemia
- Pain or cramps during insertion or following insertion
- Vaginal discharge(Leucorrhea) & infection
- Abdominal or back pain
- Leg pain & soreness
- Allergic skin reaction due to the IUD

RESIDUAL RISK

- Infection
- Patient Discomfort
- Implant failure
- Bleeding
- Pain
- Uterine Perforation
- Ectopic pregnancy
- Unwanted Pregnancy
- Allergy
- Intrauterine burns

In case of any adverse events noted, contact manufacturer or authorized representative and competent authority of the member state where user/patient is established.

MODE OF ACTION

The contraceptive activity of the IUD is mainly due to the presence of a foreign body in the intrauterine cavity. This action is reinforced in an ancillary manner by the presence of copper which is slowly released from the TCu380Ag IUD locally in the uterus. Copper is toxic to sperm and impairs sperm motility and viability, thereby preventing fertilization.

TARNISHING OF COPPER - SILVER WIRE

Copper-Silver wire bearing IUDs may show discoloration in their sterile packaging, but this should not cause alarm because the copper tarnishes causing an oxide or sulfide film to form on the surface.

If the package is not damaged and the insert before date on the package has not expired, the IUD will be sterile even if the copper on the device is tarnished. Laboratory studies show the tarnishing does not affect the safety or effectiveness of the IUD.

PRESENCE OF DEHP :

The Flange of the insertion tube is composed of PVC which contains DEHP as a Plasticizer However since the contact time of the Flange with the mucosal surface is extremely low hence no risk is posed to the woman.

Contraceptive effectiveness of TCu380Ag is 99%

CLASSIFICATION AND PACKAGING

The IUDs are Class III medical devices as per Rule 14 of Annex VIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices (MDR 2017/745).

Labelling: CE since 2012

Each sterile package contains a single, single-use device, the insertion limit date of which is indicated on the box.

The IUD, its accessories and hysterometer must be eliminated after use, as per national regulation for disposal.

Storage Conditions:

Store at 15°C to 30°C in a dry place away from direct sunlight, sources of heat, water and mechanical damage.

Shelf Life : 5 years

1	2	3	4	5	6	7
LOT	IND	Use - by Date	Do not Reuse	Caution	STERILE R	
Batch Code	Country & Date of manufacture				Sterile and Method of sterilization "R" stales Sterilization by Radiation Method	Manufacturer
8	9	10	11	12	13	14 15
CE 2460						UDI MD
CE mark	Keep Dry	Do not use if package is damaged and consult instructions for use	Keep away from sunlight	Do not re sterilize	Temperature Limit	UDI Medical Device
16	17	18	19	20	21	22
EU REP			DEHP		MR	
Authorized Representative in the European Community	Consult Instructions for Use	Single sterile barrier system	presence of phthalates (DEHP)	Medical Substance	The medical device is MR safe	contains hazardous substances

MADE WITH PRIDE IN INDIA

Legal Manufacturer

SMB CORPORATION OF INDIA

(An ISO 13485:2016 / ISO 14001:2015 Certified Company)

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CE In Progress

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