EC Design Examination Certificate

Certificate No.:
11244-2017-CE-IND-NA-PS Rev. 4.0

Project No.:
PRJC-206648-2010-PRC-IND

Valid Until:
27 May 2024

This is to certify that:

Intrauterine Contraceptive Device: Copper T 380A, Copper T 380A with Safe Load

Manufactured by:

Pregna International Ltd.

Plot No. 219, Survey No. 168, Dabhel Industrial Co-Operative Society Ltd., Dabhel, Daman (U.T)-396210, India

Has been assessed with respect to:

examination of the design of the product as described in Annex II section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 11 May 2021

Digitally signed by Vidiborschii Vladimir
Date: 2023.10.06 16:53:52 EEST
Reason: MoldSign Signature
Location: Moldova

For the issuing office:
Notified Body 2460
DNV Product Assurance AS

Palani Damodharan
Principal Assessor

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Supersedes DNV GL (NB 0434) EC Design Examination Certificate Approval no. 4317-2014- CE-IND-NA-D rev. 2 following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	09 Oct 2017
1.0	Following EC Certificate revised due to extension of brands	24 Jan 2018
2.0	Following EC Certificate revised due to extension of brands	02 May 2018
3.0	Recertification	27 April 2021
4.0	**Editorial changes**	11 May 2021

Products covered by this Certificate:

Type of medical device and identification no.:	Medical Device Class:	GMDN code:
A) Intrauterine Contraceptive Device: Copper T 380A Brand: Pregna Model T Cu 380A,Securit T IUD Model T Cu 380A,MyChoice IUD Model T Cu 380A Althea T Cu 380A,Longact T Cu 380A,Pregna+ T-Kare Model T Cu 380A,Pregna+ T Cu 380A Andalan T Cu 380A,OK IUCD T Cu 380A Lydia Copper T Cu 380A,Heer T Cu 380A Plus Pregna Standard T Cu 380A,Pregna T Care T Cu 380A,Opset Model Copper T 380A,Trust Copper T Cu 380A,Andalan Classic Cu 380, Dispositivo Intrauterino New Choice Model T Cu 380°,Elenora + T Cu 380A,Lana T T Cu 380A,Lana T Plus T Cu 380A	III	35125

B) Copper T 380A with Safe Load Pregna Model T Cu 380A with Safeload,Safeload T Cu 380A,Andalan Safeload T Cu 380A,Etherena T Cu 380A,Heer T Cu 380A Safeload,Lydia T Cu 380A Safeload, Pregna Safeload T Cu 380A,Pregna Feminin Safeload T Cu 380A Trust T Cu 380A Safeload, Freedom 10 Copper T 380A with Safeload, Aleze Safeload TCu380A Elenora Safeload, T Cu 380 A Andalan Classic Cu 380 Dispositivo Intrauterino Safeload, Lana TS T Cu 380A with safeload, Etherena T Cu 380A with Disposable Uterine Sound		

Short description of the Medical Device:

The stem of a moulded plastic T frame is wound with a spooled copper wire. The copper wire is made from Cu OFHC 99.99% pure and the size is 0.254 mm in diameter. In addition, for Copper T 380A a copper sleeve containing approximately 66.5 mg copper is placed on each horizontal arm of T frame. The total exposed surface area of the copper on the T frame is 380 mm2. A suture thread made of medical grade plastic is attached to the T frame.
The device is sterilised with radiation.
The device is class III under rule 13 and a scientific opinion for the usefulness of the medicinal substance with ancillary effect has been sought as per Annex I, clause 7.4 and a positive opinion was received.
REF Certificate No.: 11233-2017-CE-IND-NA-PS Rev. 7.0

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform the Notified Body of any intended change of the products detailed above and the Notified Body will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System. When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number.

End of Certificate