EC CERTIFICATE
Full Quality Assurance System

Certificate No.:
11233-2017-CE-IND-NA-PS Rev. 7.0

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

Valid Until:
27 May 2024

This is to certify that the quality system of:

PREGNA INTERNATIONAL LTD.

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

For design, production and final product inspection/testing of:

STERILE INTRAUTERINE CONTRACEPTIVE DEVICES

Has been assessed with respect to:

the conformity assessment procedure described in Annex II 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 16:53:44 EEST
Reason: MoldSign Signature
Location: Moldova

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

Palani Damodharan
Principal Assessor

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

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) certificate No. 4315-2014-CE-IND-NA Rev. 2.0 following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	2017-10-09
1.0	Addition of new brand name	2018-01-24
2.0	Addition of new brand name	2018-05-02
3.0	Addition of new brand name	2020-01-31
4.0	Addition of new accessory	2020-04-27
5.0	Addition of new brand Silverline Cu 380 Ag with Loader	2021-03-27
6.0	Recertification	2021-04-27
7.0	**Editorial changes**	2021-05-11

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Intrauterine Contraceptive Device with Copper	Copper T 380 A • 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	III*

	• 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	
Sterile Intrauterine Contraceptive Device with Copper	Copper T 380A with Safeload • 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	III*
Sterile Intrauterine Contraceptive Device with Copper	Cu 375 • Pregna Model Cu 375 • U-Kare Model Cu 375 • Inara Model Cu 375 • Althea Cu 375 • OK Cu 375 • LIBERTA Model Cu 375 • Protect 5 Cu 375	III**

	• Opset Cu 375 • INARA ESTANDAR • Andalan Comfort Cu375 Dispositivo Intrauterino • Pregna Cu375 • Cupraluna Omega Cu 375 • Elenora Cu 375 • Lana U Cu 375	
Sterile Intrauterine Contraceptive Device with Copper	Cu 375 Sleek • Pregna Model Cu 375 Sleek • Inara Model Cu 375 Sleek • Andalan Cu 375 Sleek • Heer Cu 375 Sleek • Lydia Cu 375 Sleek • U Kare Sleek Cu 375 • Sakhi Model Cu 375 Sleek • Trust Cu 375 Sleek • Inara Corto Cu 375 • U Care Corto Cu 375 Sleek • Andalan Comfort Mini Cu 375 Dispositivo Intrauterino • Elenora Cu 375 Sleek • Lana M Mini Cu 375	III**
Sterile Intrauterine Contraceptive Device with Copper and silver	Cu 380 Ag • Silverline Cu 380 Ag • Andalan Silverline Cu 380 Ag • Silverline 380 • Feminin Silver Cu 380 Ag • Silvercare Cu 380 Ag • Trust Plus Silverline Cu 380 Ag • Opset Cu 380 Ag • Andalan Silverflex Cu 380 Dispositivo Intrauterino • Cupraluna Silver Cu 380 Ag • Elenora Silverline Cu 380 Ag • Lana V Cu 380 Ag • Silverline Cu 380 Ag with Loader • **Silverline Cu 380 Ag with Disposable Uterine sound**	III***

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 11244-2017-CE-IND-NA-PS Rev 4.0

**Design assessment is covered by a separate EC-Design Examination Certificate No.: 11245-2017-CE-IND-NA-PS Rev 4.0

***Design assessment is covered by a separate EC-Design Examination Certificate No.: 11246-2017-CE-IND-NA-PS Rev 5.0

Sites covered by this certificate

Site Name	Address
PREGNA INTERNATIONAL LTD.	Plot No. 219, Survey No. 168, Dabhel Industrial Co-Operative Society Ltd., Dabhel, Daman (U.T)-396210, India

EU Representative

Medical Technology Promedt Consulting GmbH , Altenhofstrasse 80, D-66386 , St. Ingbert , Germany

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 updating of the quality system and the Notified Body will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. The Notified Body reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

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