

# EC Certificate

## Full Quality Assurance System

Certificate No.:  
**11233-2017-CE-IND-NA-PS Rev. 0.0**

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

Valid Until:  
**04 December 2021**

This is to certify that the quality system of:

### **Pregna International Ltd. - Daman**

Plot No. 219, 396 210, DAMAN (U.T.), 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 Article 11.1.a and Annex II (Module H1) 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, 9<sup>th</sup> October 2017**

For:  
**DNV GL NEMKO PRESAFE AS**



**Villy Rønneberg**

The Certificate has been digitally signed.  
See [www.presafe.com/digital\\_signatures](http://www.presafe.com/digital_signatures) for more info

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

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**4 December 2021**

### 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

### Products covered by this Certificate:

Product Description	Product Name	Class
<b>Sterile Intrauterine Contraceptive Device with Copper</b>	Copper T 380 A <ul style="list-style-type: none"> <li>• Pregna Model T Cu 380A</li> <li>• Securit T IUD Model T Cu 380A</li> <li>• MyChoice IUD Model T Cu 380A</li> <li>• Althea T Cu 380A</li> <li>• Longact T Cu 380A</li> <li>• Pregna+ T-Kare Model T Cu 380A</li> <li>• Pregna+ T Cu 380A</li> <li>• Andalan T Cu 380A</li> <li>• OK IUCD T Cu 380A</li> <li>• Lydia Copper T Cu 380A</li> <li>• Heer T Cu 380A Plus</li> <li>• Pregna Standard T Cu 380A</li> <li>• Pregna T Care T Cu 380A</li> <li>• Opset Model Copper T 380A</li> <li>• Trust Copper T Cu 380A</li> <li>• Andalan Classic Cu 380 Dispositivo Intrauterino</li> </ul>	III*
<b>Sterile Intrauterine Contraceptive Device with Copper</b>	Copper T 380A with Safeload <ul style="list-style-type: none"> <li>• Pregna Model T Cu 380A with Safeload</li> <li>• Safeload T Cu 380A</li> <li>• Andalan Safeload T Cu 380A</li> <li>• Etherena T Cu 380A</li> <li>• Heer T Cu 380A Safeload</li> </ul>	III*

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	<ul style="list-style-type: none"> <li>• Lydia T Cu 380A Safeload</li> <li>• Pregna Safeload T Cu 380A</li> <li>• Pregna Feminin Safeload T Cu 380A</li> <li>• Trust T Cu 380A Safeload</li> <li>• Freedom 10 Copper T 380A with Safeload</li> <li>• Aleze Safeload TCu380A</li> </ul>	
<p><b>Sterile Intrauterine Contraceptive Device with Copper</b></p>	<p>Cu 375</p> <ul style="list-style-type: none"> <li>• Pregna Model Cu 375</li> <li>• U-Kare Model Cu 375</li> <li>• Inara Model Cu 375</li> <li>• Althea Cu 375</li> <li>• OK Cu 375</li> <li>• LIBERTA Model Cu 375</li> <li>• Protect 5 Cu 375</li> <li>• Opset Cu 375</li> <li>• INARA ESTANDAR</li> <li>• Andalan Comfort Cu375 Dispositivo Intrauterino</li> <li>• Pregna Cu375</li> </ul>	<p>III*</p>
<p><b>Sterile Intrauterine Contraceptive Device with Copper</b></p>	<p>Cu 375 Sleek</p> <ul style="list-style-type: none"> <li>• Pregna Model Cu 375 Sleek</li> <li>• Inara Model Cu 375 Sleek</li> <li>• Andalan Cu 375 Sleek</li> <li>• Heer Cu 375 Sleek</li> <li>• Lydia Cu 375 Sleek</li> <li>• U Kare Sleek Cu 375</li> <li>• Sakhi Model Cu 375 Sleek</li> <li>• Trust Cu 375 Sleek</li> <li>• Inara Corto Cu 375</li> <li>• U Care Corto Cu 375 Sleek</li> <li>• Andalan Comfort Mini Cu 375 Dispositivo Intrauterino</li> </ul>	
<p><b>Sterile Intrauterine Contraceptive Device with Copper and silver</b></p>	<p>Cu 380 Ag</p> <ul style="list-style-type: none"> <li>• Silverline Cu 380 Ag</li> <li>• Andalan Silverline Cu 380 Ag</li> <li>• Silverline 380</li> <li>• Feminin Silver Cu 380 Ag</li> <li>• Silvercare Cu 380 Ag</li> <li>• Trust Plus Silverline Cu 380 Ag</li> <li>• Opset Cu 380 Ag</li> <li>• Andalan Silverflex Cu 380 Dispositivo Intrauterino</li> </ul>	



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\* Design assessment is covered by a separate EC-Design Examination Certificate No.: 11244-2017-CE-IND-NA-PS Rev 0.0

\*\*Design assessment is covered by a separate EC-Design Examination Certificate No.: 11245-2017-CE-IND-NA-PS Rev 0.0

\*\*\*Design assessment is covered by a separate EC-Design Examination Certificate No.: 11246-2017-CE-IND-NA-PS Rev 0.0

The complete list of devices is filed with the Notified Body

### **Sites covered by this certificate**

Pregna International Ltd. – Daman  
Plot No. 219, Survey No. 168, Dabhel Co-Op Ind. Soc. Ltd., Dabhel,  
Daman (U.T.) - 396 210, India

### **EU Representative**

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

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### 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 Presafe of any intended updating of the quality system and Presafe 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. Presafe 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 of Presafe.

End of Certificate