

DECLARATION OF CONFORMITY

Application of European Union Council Directive 93/42/EEC as amended by 2007/47/EC

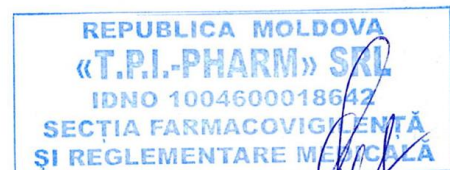
Certificate No.	PILD/DOC/ CopperT380AwithSafeload /2021-2022/004
Manufacturer	PREGNA INTERNATIONAL LTD. Plot No. 219, Survey No. 168, Dabhel Industrial Co-Operative Society Ltd., Dabhel, Daman (U.T) - 396210, India
European Union Authorized Representative	Medical Technology Promedt Consulting GmbH, Altenhofstrasse 80, D-66386 St. Ingbert, Germany Tel:- +49-(0) 6894 581020 Fax:- +49 (0) 6894 581021 Email:- info@mt-procons.com
Country	Moldovo
Product	Sterile Intrauterine Contraceptive Devices - Copper T 380A with Safeload
Model/Type	Etherena T Cu 380A with Disposable Uterine Sound
Batch Details	DAT 2567 (Mfg. Date : 2021-02 Exp. Date: 2026-01) DAT 2568 (Mfg. Date : 2021-02 Exp. Date: 2026-01)
Device Classification	Class III, According to 93/42/EEC, Annex : IX, Rule No.:13
Conformity Assessment Route	Annex II Including section 4 (Module H1) of Council Directive 93/42/EEC on Medical Devices
GMDN Codes	35125
UMDNS Codes	12156

We hereby declare that the above-mentioned product complies with the Essential requirements of MDD 93/42/EEC as defined in Annex I of the directive. This declaration of conformity is issued under sole responsibility of manufacturer.

Standards Applied	EN 556-1:2001, EN 556-2:2015, EN 1041:2008, ISO 7439:2015, EN ISO 9001:2015, EN ISO 10993-1:2009, EN ISO 10993-3:2014, EN ISO 10993-5:2009, ISO 10993-10:2010, EN ISO 10993-11:2018, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 13485:2016, EN ISO 14155:2011, ISO 14644-1:2015, ISO 14644-2:2015, EN ISO 14971:2012, EN ISO 15223-1:2016, IEC 62366-1:2015, WHO UNFPA specification for Copper T 380A 2016.
Notified Body	DNV GL PRESAFE AS Veristasveien 3, N-1363 Høvik, Norway. Reg. Enterprises No. NO 997 067 401 M Notified Body Number: 2460
EC Certificate	11233-2017-CE-IND-NA-PS Rev. 7.0 , Date of Issue: 11 May 2021
EC Design Examination Certificate	11244-2017-CE-IND-NA-PS Rev. 4.0



Mr. Ranjit Gaikwad
DGM - Quality Assurance & Regulatory Affairs
Date: 14/05/2021



Factory :- Plot No. 219, Survey No. 168, Dabhel Co. Op. Ind. Soc. Ltd., Dabhel, Daman (U.T.) - 396 210.

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CIN No. is U25209MH1993PLC073582