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To BECOR COMPANY (REPUBLIC OF MOLDOVA)

EC DECLARATION OF CONFORMITY

CEX INTERNACIONAL S.A. addressed in **C/Canigó, 6 - Llerona - 08520 LES FRANQUESES DEL VALLÈS (BARCELONA) SPAIN.**

DECLARES:

- **The natural rubber latex probe covers for vaginal and anal ultrasound scanning** described below meet the essential requirements, which apply to them, set out in Annex I of Council Directive 93/42/EEC of 14 June 1993 concerning medical devices and their latest amendments.

- **The natural rubber latex probe covers for vaginal and anal ultrasound scanning** of **Class IIa** are manufactured in conformity with the technical documentation referred to in Section 3 of Annex VII of Council Directive 93/42/EEC.

- The Quality Management System approved for the manufacture and carry out the final inspection of **natural rubber latex covers for vaginal and anal ultrasound scanning,** set out in Annex V of Council Directive 93/42/EEC, has been evaluated by the **Notified Body No. 0318** as per our **EC Production Quality Assurance Certificate No. 97 01 0025 CP** that guarantees the conformity of products with the applicable requirements of Council Directive 93/42/EEC.

PRODUCT: *NATURAL RUBBER LATEX PROBE COVER FOR VAGINAL AND ANAL ULTRASOUND SCANNING.*

CLASS: *IIa* *GMDN Code: 44712*

DESCRIPTION: *SMOOTH, PARALLEL-SIDED, WITHOUT TIP END AND TRANSPARENT COLOUR.*

BRAND NAME:

ECOFUNDA

Approved by,

Cex Internacional S.A. C/ Canigó, 6 - Llerona 08520 Les Franqueses del Vallès Barcelona (Spain) Tel. 93 849 80 33 Fax 93 849 82 67

Mr Eduardo Lagarda Gual
Managing Director
04th January 2018

Digitally signed by Azarov Tatiana
Date: 2019.12.13 15:44:51 EET
Reason: MoldSign Signature
Location: Moldova

Annexes V and VII (Council Directive 93/42/EEC)

ROMED HOLLAND
Declaration of conformity

Manufacturer	**Van Oostveen Medical BV** **Herenweg 269** **3648 CH Wilnis** **Netherlands** **Tel: 0031 297 282101** **Fax: 0031 297 288316** **e-mail: info@romed.nl** **website: www.romed.nl**
Validity of this declaration of conformity until	29 July 2016
Product	Cleansing wipes (ABW)
Brand	ROMED
Classification (MDD, Annex IX)	I

We, with sole responsibility in drawing up this declaration of conformity, declare that the above mentioned product meets the provisions of the following EC Council Directives and Standards. All supporting documentation is retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives :

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC) as amended by council directive MDD 2007/47/EEC.

Standards

Harmonised Standards (published in the Official Journal of the European Communities) applicable to this product.

Wilnis, The Netherlands, 2021

ROMED - HOLLAND PRODUCTS

M.J. van Oostveen
Managing Director