



DECLARATION OF CONFORMITY



MANUFACTURER	CEX Internacional, S.A. C/Canigó, 6 – Llerona 08520 Les Franqueses del Vallès (Barcelona) Spain
PRODUCT	Latex probe cover for vaginal and / or anal ultrasound scan
MODELS	Smooth, straight walled, without reservoir, and transparent Smooth, straight walled, without reservoir, transparent, and lubricated
CATALOG REFERENCES	29509, 29510, 29513, 29514
TRADEMARKS	ECOFUNDA
CLASS, RULE	Ila, 5
ROUTE OF THE CONFORMITY EVALUATION	Annex II.3 of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
NOTIFIED BODY	Centro Nacional de Certificación de Productos Sanitarios, CNCps NB No. 0318
CE CERTIFICATE	Full quality assurance system in accordance with Annex II, except Section 4, of Directive 93/42/EEC No. 2020 04 0907 CT
CERTIFICATE VALIDITY	Until 26/05/2024

Declaration

We hereby declare under our responsibility that the above-mentioned products meet all the requirements that apply to them under Directive 93/42/EEC on Medical Devices.

This product has not undergone any significant change in its design or its purpose of use after May 26, 2021.

Approval date: 19/04/2023

Signed:



Eduard Lagarda Vila
CEO