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EC DECLARATION OF CONFORMITY

MANUFACTURER

CEX INTERNACIONAL S.A.

C/Canigó, 6 - Llerona - 08520 LES FRANQUESES DEL VALLÈS (BARCELONA) Spain.

MEDICAL DEVICE

Product: NATURAL RUBBER LATEX PROBE COVER FOR VAGINAL OR ANAL
ULTRASOUND SCANNING.

Brand Name ECOFUNDA

Risk Classification: Class IIA (Rule 5)

The manufacturer hereby declares under his sole responsibility that the Medical Device(s) specified above and provided with the CE marking comply with all requirements of the Council **Directive 93/42/EEC** of 14 June 1993 concerning medical devices, **Annex II (except section 4)**, and the following standards in the European Community which applies to the product.

The declaration is supported by the following certificate(s) according to the provisions of relevant annex(es) of above Directive.

QUALITY MANAGEMENT SYSTEM CERTIFICATE

Directive or Regulation: Directive 93/42/EEC
Conformity assessment route: Annex II (except section 4)

Quality system: Certificate EN ISO-13485 **Nº 2011 12 0002 EN**
(Validity date: 25-02-2022).

EC Mark: EC Full Quality Assurance System Certificate **Nº 2020 04 0907 CT**
Validity date: 26-05-2024).

Notified Body: NB0318
Agencia Española de medicamentos y productos sanitarios (AEMPS)

No application has been lodged with any other notified body for the same product-related quality system

STANDARDS APPLIED

EN ISO 13845 / EN ISO 4074 / EN ISO 14971 / EN ISO 15223-1 / EN ISO 10993-5 / EN ISO 10993-10

This declaration of conformity is valid from:

(or until a revised declaration is made due to products modifications)

Authorised Signatory:

Identification of Signer:

Title:

01/06/2020



Eduard Lagarda Vila

C.E.O.