



EU DECLARATION OF CONFORMITY

MANUFACTURER

CEX Internacional, S.A.
C/Canigó, 6 – Llerona
08520 Les Franqueses del Vallès (Barcelona)
Spain

SRN (Single Registration Number)

ES-MF-000000392

PRODUCT

Latex probe cover

Intended purpose

Prevention of transmission of microorganisms due to cross-contamination during a vaginal or rectal ultrasound

Basic UDI-DI

8413554Z110401850000006WS

MODELS

Natural rubber latex probe cover for vaginal and / or anal ultrasound scanning

TRADEMARKS

ECOFUNDA

REFERENCES

PF-ECO-10 ECOFUNDA 500 UN.
PF-ECO-14 ECOFUNDA 1.000 UN (10 x 100)
PF-ECO-18 ECOFUNDA 50 UN

RISK CLASS

Class I, Annex VIII, Chapter 3, Paragraph 5, Rule 5

ROUTE OF THE CONFORMITY EVALUATION

Article 19 and Annex IV of the Regulation (EU) 2017/745 – Self-certification

Declaration

This EU declaration of conformity is issued under the sole responsibility of CEX Internacional, S.A.

The product object of the declaration is in conformity with the Regulation (EU) 2017/745 on Medical Devices.



Eduard Lagarda Vila
CEO

Xavier Guerrero Cano
Person Responsible for Regulatory Compliance

*Signed in Les Franqueses del Vallès
On May 16, 2024*