

Regulatory Compliance Certificate & EU Declaration of Conformity

This document serves as the official Declaration of Conformity for Cathetrix Ltd, confirming that the **Foley-Safe** medical device meets all requirements of the EU MDR 2017/745. It includes entity profiles, product identifiers, and a comprehensive matrix of applied international standards.

Entity Profiles & Product Identity

Manufacturer: Cathetrix Ltd, 7 Yahalom St., Yahud Monoson, 6019000, Israel. SRN: IL-MF-000036429 | tal@cathetrix.com.

EU Authorized Representative: MedNet EU-REP GmbH, Borkstrasse 10, 48163 Münster, Germany. SRN: DE-AR-000000002 | contact@mednet-eurep.com.

Device Overview: Foley-Safe is a urinary catheter securement and cutting device, designed to enhance patient safety by preventing unintended catheter displacement and reducing the risk of injury.

Classification: Class I (MDR Annex VIII, Rule 1).

EMDN Code: U0280 (Urethral Catheters and Stants Accessories).

Basic UDI: 7290017937CAT85.

Product Variants

Cat No.	UDI-DI	Product Name	Units
CS-5000	07290017937007	Foley-Safe	1
CS-5210	17290017937004	Foley-Safe	10
CS-5220	27290017937001	Foley-Safe	200

Regulatory Compliance & Standards Matrix

Compliance Statement: Cathetrix Ltd declares under her sole responsibility for conformity with EU MDR 2017/745, Annex IX. Risk Classification is in accordance with EU MDR 2017/745, Annex VIII.

Applied Regulatory Standards: Comprehensive adherence to international safety, quality, and material specifications:

Quality & Risk Management:

EN-ISO 13485:2016/A11-2021, EN-ISO 14971:2019/A11-2021, TR/ISO 24971:2020.

Safety & Labeling Standards:

Biological & Material Safety: EN ISO 10993-1:2018, ASTM A582/A582M – 12(2017), ASTM F623-2019.

Labeling & Information: EN ISO 15223-1:2021, EN ISO 15223-1:2021/A1:2025, EN ISO 20417:2021.

Kfir Elrom - C.E.O

