Appendix 1 to TF1011-04

Declaration of Conformity (MDR)- Efemia Bladder support

Manufacturer
Invent Medic Sweden
Nytänkargatan 4
SE-22363 Lund, Sweden

SNR: SE-MF-000001841

Inhouse product name:
TVS 30 mm
TVS 35 mm
TVS 40 mm
TVS 30, 35 and 40 mm Start set

Commercial name(s);
110107 Efemia Bladder Support 30 mm
110207 Efemia Bladder Support 35 mm
110307 Efemia Bladder Support 40 mm
110409 Efemia Bladder Support Start set

Basic UDI
73501006300159

Intended Purpose
Invasive non-active medical devices intended to temporarily reduce stress induced urine leakage in women.

Risk Classification
Class IIb device according to rule 5

Invasive device with respect to body orifices, other than surgically invasive, for long-term use

Declaration
The undersigned hereby declares that Efemia Bladder Support is in conformity with MDR 2017-745 of the European Parliament and of the Council on medical devices. No other legislation requiring a declaration of conformity is applicable.
This Declaration of Conformity is issued under the sole responsibility of Invent Medic Sweden.

Applied harmonized standards and Consensus Standards

EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019	Medical devices – Application of risk management to medical devices
EN ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice
ISO 15223-1:2021	Medical Devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 20417:2021	Medical devices – Information to be supplied by the manufacturer
EN 62366:2015	Medical devices - Application of usability engineering to medical devices

Conformity assessment procedure
Regulation (EU) 2017-745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb devices) – No. G10 111643 0002 (TÜV SÜD)

Lund 2024-08-13

Date

Åsa Westrup,
Director Quality and Regulatory Management, Invent Medic Sweden AB