andromedical

EU DECLARATION OF CONFORMITY

CE

Identification of the declarant and manufacturer:

Name Andromedical S.L.
Address Gran via 6, 28013 Madrid, Spain
VAT ESB82545096
Email legal@andromedical.com

Product identification:

Product description Penile traction device (PTD)
Product name Andropenis
Models, Basic UDI-DI & Intended Use

Androkit Accessories	84370049882732VS	Penile traction device accessories
Androcomfort	84370049882730VN	Penile traction device accessories
Androsilicone	84370049881017UL	Penile traction device accessories
Androring	84370049881204UM	Penile traction device accessories
Androtop	84370049881018UN	Penile traction device accessories
Androkit Parts	84370049882665W4	Penile traction device rods
Androrod assembled	84370049881914VT	Penile traction device rods
Androrod large	84370049882975WN	Penile traction device rods

Classification Medical Device Class I
Device Type: Non-sterile, non-measurement, non-reusable surgical instrument, non-invasive, non-incorporated medical substances, and non-active.
EMDN Code U99, Devices for urogenital system - Other
GMDN Code 46340, Penile traction splint.
UMDNS Code 23850, Penile tissue expanders, traction.
Market Notifications RPS/197/2022, RPS/4154/2022, RPS/4155/2022, RPS/4156/2022.
GHTF Risk Class A, Low Risk.
Test-Standards ISO 10993; EN71-3:2002. Serial production.

The Product to which this declaration on refers to, is manufactured according to the Medical Device Regulation (EU) 2017/745 and is registered in Class I according to Annex VIII, Chapter III, Rule 1. Conformity is assured according to the guidelines set out in Annex X. The Product is produced in accordance with harmonized standards. The product carries the CE Mark. Notified body intervention is not required.

The manufacturer, hereby, bears full responsibility for the production in accordance with the requirements stated in this declaration.

Place and Date: Madrid, 03/03/2023

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DocuSigned by:
Eduardo Gómez de Diego
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Dr. Eduardo Gómez de Diego, CEO & QA/RA Rep.

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