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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		
Andropenis Gold	84370049882798WQ	Penile lengthening for sensitive skin
Andropenis Pro	84370049882920VV	Penile lengthening for regular penis
Andropenis Mini	84370049882002UE	Penile lengthening for micropenis
Andropenis Extra	84370049883059VJ	Penile lengthening for macropenis
Andropeyronie	84370049882947WH	Peyronie's disease & penile curvature
Androsurgery	84370049882797WN	Penile shortening prevention
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/39/2022, RPS/40/2022, RPS/41/2022, RPS/4146/2022.	
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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