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
Product models	Gold, Mini, Pro (Androextender)
Classification	Medical Device Class I
Type:	Non-sterile, Non-measurement, Non-reusable surgical instrument, non-invasive, non-incorporated medical substances, non-active, device.
Test-Standards	ISO 10993; EN71-3:2002
GMDN Code	46340, Penile traction splint.
UMDNS Code	23850, Penile tissue expanders, traction.

The Product to which this declaration on refers to, is manufactured according to the Medical Device Regulation (EU) 2017/745 on the approximation of the laws of Member States and is registered in Class I according to Annex VIII. 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, 10/10/2020

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

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