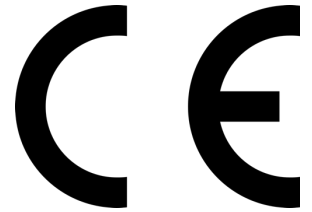




EU DECLARATION OF CONFORMITY



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 Vacuum erection device (VED)
Product name Androvacuum
Product models Premium, Pro
Classification Medical Device Class IIa
Type: Non-sterile, Non-measurement, Non-reusable surgical instrument, non-invasive, non-incorporated medical substances, active, device.
Test-Standards EN55014-1 2006+A1:2009+A2:2011
EN55014-2 1997+A1:2001+A2:2008
GMDN Code 17744, Penile rigidity devices
UMDNS Code 17744, Penile vacuum devices

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

92E83BD67AB94FE...



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

www.andromedical.com

Phone-Fax: +34-911-981-740

Gran via 6
28013 Madrid
SPAIN