



## EU DECLARATION OF CONFORMITY



### Identification of the declarant and manufacturer:

**Name** Andromedical S.L.  
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### Product identification:

**Product description** Vacuum erection device (VED)  
**Product name** Androvacuum  
**Product models** Androvacuum Premium, Andropump  
**Classification** Medical Device Class I, Non-sterile, Non-measurement, Non-reusable surgical instrument  
**Test-Standards** EN55014-1 2006+A1:2009+A2:2011  
EN55014-2 1997+A1:2001+A2:2008  
**GMDN Code** 17744, Penile rigidity device

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 & Date: Madrid, 14th November 2019

  


Dr. Eduardo Gómez de Diego

CEO & CRO

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