

Declaration of Conformity

(according to Regulation (EU) 2017/745 on medical devices, annex IV dated May 2017)

be-on-market GmbH
SRN: DE-MF-000006151

Lilienstraße 33
91244 Reichenschwand
Germany

declares under its sole responsibility that the product

BASIC-UDI-DI: 426067671_promano_8D

Product: Promano

Promano is a software application for patients' mobile devices for the treatment of erectile dysfunction.

SW main version: 1.X.Y

to which this declaration relates is in conformity with the following regulation:

Evaluation procedure according to Regulation (EU) 2017/745 on medical devices, annex IV and related laws

Classification according to Regulation (EU) 2017/745 on medical devices, annex VIII:

Software Rule 11c Class I

This product has been CE-labelled due to the fulfilment of the general safety and performance requirements according to Regulation (EU) 2017/745 on medical devices, annex I.



be-on-market GmbH, Jan Knittel, PRRC, Reichenschwand