

EC Certificate

according to regulation (EU) 2017/745 of the European
Parliament and of the Council of 5 April 2017 on Medical Devices

The company **Mera Medical Solutions, S.L.**, located at Troya Street nº 18, Pavilion 6-A5 in 20115 Astigarraga (Gipuzkoa – Spain), is the manufacturer of the **HAREX medical device**, an external device intended to control male urinary incontinence, and which is a **Class I medical device** according to Annex VIII of the EU Regulation 2017/745 on medical devices.

We hereby declare, on our sole responsibility, the conformity of the abovementioned medical device in accordance with Regulation (EU) 745/2017 of the European Parliament and of the Council of 5 April 2017 on medical devices and has therefore obtained the **CE marking self-certification**.

Lead Competent Authority:

AEMPS - Spain Medicines & Healthcare Products Regulatory Agency

License number:

7445-PS

Signed on behalf of MERA MEDICAL SOLUTIONS, S.L.

Peio Tomé

Astigarraga – Spain
29, June, 2021



Owner/Managing Director

Place, Date

Signature