Mera
Medical Solutions S.L.

EU Declaration of Conformity

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

Medical Device:	HAREX
Manufacturer:	**Mera Medical Solutions, S.L.** Troya Street 18, Pavilion 6-A5 20115 Astigarraga - Gipuzkoa Spain
Basic UDI-DI:	8437019807HAREX8R
MDR Classification: **(risk class)**	Class I (non-sterile condition, non-measuring function)
SRN:	Not yet available
Intended Porpouse:	Harex is an external device intended for the control of male urinary incontinence. Harex device is placed just below the head of the penis an by means of a gentle pressure on urethra, it prevents an controls the involuntary urinary leakages.

We hereby declare, on our sole responsibility, the conformity of the abovementioned medical device in accordance with Regulation (EU) 2017/745 of the European Parliament of 5 April 2017 on medical devices and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Mera Medical Solutions, S.L., the subject of this Declaration, is in accordance with the following harmonised European standards.

HARMONISED STANDARDS	
Code:	**Title**
UNE EN ISO 13485:2016	Medical Devices, Quality Management Systems. Requirements for regulatory purposes.

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

Peio Tomé	Astigarraga – Spain 29, June, 2021	
Owner/Managing Director	**Place, Date**	**Signature**