

EU DECLARATION OF CONFORMITY

Manufacturer:	JMS CO., LTD. 12-17 Kako-machi, Naka-ku, Hiroshima-shi, Hiroshima 730-8652 Japan SRN : JP-MF-000021805
Authorized representative:	Bionic Medizintechnik GmbH Max-Planck-Straße 21,61381 Friedrichsdorf, GERMANY SRN : DE-AR-000012049
Basic UDI-DI:	4987494001EU
CND code_/ name:	Code : V030299 Name : CLINICAL MEASUREMENT SYSTEMS
Product category:	MDN code : MDN1214 Type : General non-active non-implantable devices used in health care and other non-active non-implantable devices
Product name:	JMS Tongue Pressure Measurement Device (Model name: Connecting Tube)
Trade name	JMS Tongue Pressure Measurement Device (Model name: Connecting Tube)
Intended purpose:	Connect Digital Tongue Pressure Meter and Tongue Pressure Probe.
Affective products:	Refer to the attachment A
Risk class / Rule applied:	Class: I / Rule: 1
Applied standards:	Refer to the attachment B

This EU declaration of conformity is issued under the sole responsibility of JMS CO., LTD as the manufacturer of these medical products.

We, JMS CO., LTD. ensure and declare that the above products meet all provision of the Regulation (EU) No. 2017/745 and, if applicable, with any other relevant Union legislation that provides for the issuing of an declaration of conformity which apply to them. The lot number mentioned is the first lot which comply with the Regulation. All lots manufactured later than this lot are also comply with the Regulation.

Notified body/ID No.:	N/A
Conformity assessment procedure:	Annex : <u>II/III</u>
Certificate number/ Date of issue:	N/A
Signature:	<u>Shohei Irie</u> Date <u>2022.6.17</u> Name: <u>入江 秀和</u> Function: <u>Person responsible for regulatory compliance</u>
Place:	<u>Hiroshima</u> JAPAN

Applied CS

Attachment B

Reference of the Common Specifications (CS)	Title of the CS
N/A	N/A