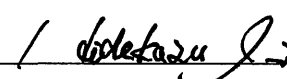


EU DECLARATION OF CONFORMITY

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 : MDA0318 Type : Other active non-implantable devices
Product name:	JMS Tongue Pressure Measurement Device (Model name: Digital Tongue Pressure Meter)
Trade name	JMS Tongue Pressure Measurement Device (Model name: Digital Tongue Pressure Meter)
Intended purpose:	The motor function of the tongue is investigated by measuring the maximum tongue pressure
Affective products:	Refer to the attachment A
Risk class / Rule applied:	Class : Im / Rule: 13
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.:	TÜV SÜD Product Service GmbH / 0123
Conformity assessment procedure:	Annex : <u>IX</u>
Certificate number/ Date of issue:	Number: G11 024761 0169 Rev. 00 / Date : 2022-03-16
Signature:	 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