


Technical Documentation	<b>ECG Electrodes</b>	<b>TD N 1-446</b>
	<b>EU Declaration of Conformity</b> <b>“swaromed”</b>	<b>Issue: 004</b>
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**EU Declaration of Conformity**

**Manufacturer:** Nissha Medical Technologies Ltd  
**SRN - GB-MF-000012507** Torbay Business Park, Woodview Road,  
Paignton, Devon, TQ4 7HP, UK

**Authorised Representative:** Nissha Medical Technologies SAS  
**SRN - FR-AR-000009795** 23-25 Boulevard de la Paix,  
95800 Cergy, France

**Product Group:** ECG-Electrodes - swaromed  
**Basic UDI-DI:** 506044191ECG-ElecCJ  
**GMDN Code:** 35035  
**Classification MDR:** Class I (Annex VIII, Rule 1)

**REF-numbers:** 1001, 1002, 1007D, 1008, 1008D, 1009, 1010, 1012, 1019, 1022, 1023, 1032, 1033, 1035, 1036, 1036E, 1036FT, 1037, 1037D, 1039, 1040, 1057, 1060, 1066, 1077, 1083, 1084, 1084FT, 1085, 1088, 1091, 1099, 1702, 4001, 4002, 4008, 4008D, 4009, 4010, 4019, 4022, 4023, 4036, 4036E, 4040, 4050, 4051, 4057, 4060, 4066, 4077, 4101, 4102, 4103, 4105, 4106, 4107, 4109, 4110, 4111, 4112, 4113, 4114, 4701, 4702, 4703, 4704

We hereby declare under our sole responsibility that the medical devices referenced above are in conformity with Regulation EU 2017/745 (MDR) and with Directive 2011/65/EU (RoHS – including amendment EU 2015/863).

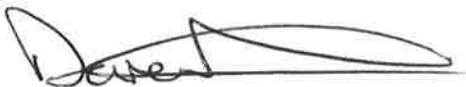
All medical devices are subject to the Quality Management System of Nissha Medical Technologies Ltd which is certified according to EN ISO 13485:2016.

The medical devices have the CE-mark.

The relevant documentation is maintained by Nissha Medical Technologies and is made available for inspection by the national authorities, the notified body and - where legally requested - by end-users and customers upon their request.

The validity of this Declaration of Conformity is in agreement with the validity period of the Quality Management System Certificate of our notified body (March 29, 2023), unless it is substituted by a new issue before this date.

Paignton, 2021-09-07



Nissha Medical Technologies Ltd.  
Daren Davies  
Quality and Regulatory Affairs Manager - UK

Nissha Medical Technologies Ltd  
Torbay Business Park  
Woodview Road  
Paignton  
Devon TQ4 7HP  
Tel: +44 (0) 1803 860100

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