Manufacturer: **SRN - GB-MF-000012057**	**Nissha Medical Technologies Ltd** **Torbay Business Park, Woodview Road,** **Paignton, Devon, TQ4 7HP, UK**
Authorised Representative: **SRN - FR-AR-000009795**	**Nissha Medical Technologies SAS** **23-25 Boulevard de la Paix,** **95800 Cergy, France**
Product Group:	ECG-Electrodes - swaromed
Basic UDI-DI:	506044191ECG-Elec1QZ
EMDN Code:	C020501
Classification MDR:	Class I (Annex VIII, Rule 1)
REF-numbers:	**1001, 1002, 1008, 1008D, 1009, 1010, 1019, 1023, 1036, 1036E, 1036FT, 1037, 1039, 1040, 1057, 1060, 1066, 1083, 1084, 1084FT, 1085, 1088, 1099, 1702, 4008, 4008D, 4009, 4010, 4019, 4023, 4036, 4036E, 4040, 4057, 4060, 4066, 4102, 4103, 4105**

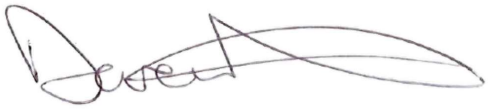
We hereby declare under our sole responsibility that the medical devices referenced above are in conformity with Regulation EU 2017/745 (MDR) and with Directive 2011/65/EU (RoHS – including amendment EU 2015/863).

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, 2026), unless it is substituted by a new issue before this date.

Paignton, 2024-07-29



Nissha Medical Technologies Ltd.
Daren Davies
Regulatory Compliance Manager