# EU Declaration of Conformity

| | |
|---|---|
| **Manufacturer:** | **Nissha Medical Technologies Ltd**<br>**Torbay Business Park, Woodview Road,**<br>**Paignton, Devon, TQ4 7HP, UK** |
| **Manufacturer SRN:** | **GB-MF-000012057** |
| **Authorized Representative:** | **Nissha Medical Technologies SAS**<br>**23-25 Boulevard de la Paix,**<br>**95800 Cergy, France** |
| **Authorized Representative SRN:** | **FR-AR-000009795** |
| **Product Group:** | GE Medical Chart Recording Paper |
| **Basic UDI-DI:** | 506044191Chart-PaperWD |
| **GMDN Code:** | 61901 |
| **Classification MDR:** | Class I (Annex VIII, Rule 1) |
| **Declaration as per MDR:** | Annex IV |

**REF-numbers:** **2104772-001, 2104775-001 & 5684683.**

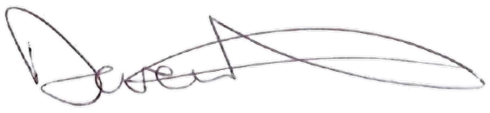
We hereby declare under our sole responsibility that the medical devices referenced above are in conformity with Regulation (EU) 2017/745 (MDR) and with Directive 2011/65/EU (RoHS - including amendment 2015/863).

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, 30th Mar 2023



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 880100