


Technical Documentation	<b>Medical Chart Recording Paper</b> <b>EU Declaration of Conformity</b>	<b>TD N 3-785</b>
		<b>Issue: 001</b>
		Page 1/2

## EU Declaration of Conformity

**Manufacturer:** Nissha Medical Technologies Ltd  
Torbay Business Park, Woodview Road,  
Paignton, Devon, TQ4 7HP, UK

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

**Product Group:** Medical Chart Recording Paper  
**Basic UDI-DI:** 506044191Chart-PaperWD  
**GMDN Code:** 61901  
**Classification MDR:** Class I (Annex VIII, Rule 1)

REF-numbers:						
0073424C	2018060C	4000840C	4004960C	4011590C	4011652C	6610526G
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2000346C	2026689C	4003695C	4007874C	4011610C	6610072G	
2000605C	2026712C	4003710C	4008437C	4011611C	6610211G	
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<b>NISSHA</b> MEDICAL TECHNOLOGIES		<b>Issue: 001</b>
		Page 2/2

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).

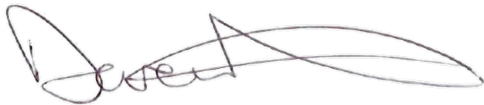
All medical devices are subject to the Quality Management System of Nissha Medical Technologies Ltd which is certified according to EN ISO 13485:2016.

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, 2021-05-24



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