

EU DECLARATION OF CONFORMITY

Zorghelden® Brand

1. Manufacturer:

Apto Enterprises

Mughal Pura Murad Pur Road, Sialkot – 51310, Pakistan

2. Designated Authorized Representative:

Mak Web

Korte putstraat 1F

5211KP

'S-Hertogenbosch

Netherlands

3. This declaration of conformity is issued under the sole responsibility of the manufacturer: We, Apto Enterprises (manufacturer), represented in the Union by Mak Web (EU Authorized Representative), hereby declare under our sole responsibility that the devices described are in conformity with the applicable Union legislation.

4. Object of the declaration (identification of product allowing traceability)

DCS/1236722553-A - Zorghelden® Nursing Devices (Class I)

This declaration applies to the following product families placed on the EU market under the Zorghelden® brand: (i) nursing scissor sets (paper-coated and plasma-coated), (ii) acoustic (non-electronic) stethoscopes, (iii) otoscopes (active devices emitting only visible light), (iv) acoustic tuning forks (various frequencies), and (v) reflex hammers. All listed products are non-sterile, non-active or active devices emitting only visible light, non-invasive (Rule 1) or transient non-surgically invasive via a body orifice (Rule 5), without a measuring function, and are classified as Class I under Regulation (EU) 2017/745.

Annexes: Annex A – Illustrative images (for identification only).

5. Union harmonisation legislation

The objects described in point 4 are in conformity with Regulation (EU) 2017/745 on medical devices (MDR) for Class I medical devices.

The device(s) bear the CE marking in accordance with Regulation (EU) 2017/745.

6. References to relevant standards/specifications used

EN ISO 13485:2016 (Medical devices — Quality management systems — Requirements for regulatory purposes).

7. Notified body involvement (where applicable)

Not applicable. For Class I devices that are non-sterile, without measuring function and not reusable surgical instruments, no notified body involvement is required per Article 52(7) MDR.

8. Additional information

Signed for and on behalf of the manufacturer by the Authorized Representative:

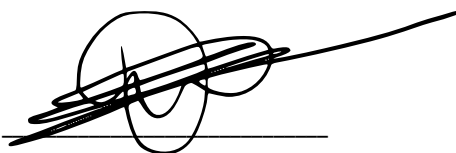
Lucas Mak van Waay - Mak Web (Authorized Representative and Importer)

Korte putstraat 1F – 5211KP 'S-Hertogenbosch – The Netherlands

Date: 2025-09-16

Place: 's-Hertogenbosch

Signature: _____

A handwritten signature in black ink, consisting of a large, stylized 'L' and 'M' followed by a horizontal line extending to the right.

Annex A: Illustrative images (for identification only)

