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Declaration of Conformity

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Version 2.1 (latest)

EU MDR

Declaration of Conformity (DoC)

This declaration is legally binding and is issued under the sole responsibility of the manufacturer named below. It served to clearly identify, and enable traceability to, the device subject to this Declaration.

Manufacturer name:

Tandem Health AB

SRN:

SE-MF-000049463

Adress:

Malmskillnadsgatan 44a 111 57, Stockholm Sweden

Telephone number:

+46844682083

E-mail address:

support@tandemhealth.ai

Device name:

Tandem AI Medical Scribe

EMDN Code:

V92, Medical Device Software – not included in other classes

MDA Code:

0315

The Tandem AI Medical Scribe is intended for use as a clinical document generation tool to assist healthcare professionals with drafting structured clinical documents from patient consultations. By automating the documentation process, the device is intended to decrease clinician time spent on documentation, enabling healthcare professionals to devote more time to direct patient care. The scribe allows users to review and edit suggested document content to ensure accurate and complete documentation of clinical findings, which informs ongoing patient management. All outputs generated by the device must be reviewed and verified by the responsible healthcare professional prior to transfer to the electronic health record.

Product risk classification:

Class IIa

Basic UDI-DI:

735017982TANDEMSCRIBEAB

UDI-DI:

07350179820033

Details of product variants:

N/A

Route to Conformity Assessment:

According to Annex IX of MDR based on a quality management system and on assessment of technical documentation.

We, Tandem Health AB, declare that the product described in this Declaration conforms to the following Regulations and standards:

European regulation (EU) 2017/745 on medical devices (MDR), as amended

Additional information:

N/A

Notified Body**Notified Body name:**

Scarlet NB B.V.

Notified Body number:

3022

Certificate number:

SCAR-9.2.1.5

Place and date of issue:

Stockholm, 30.06.2026

Signed on behalf of Tandem Health AB

A handwritten signature in black ink, appearing to be 'Y. Peng Zhao', written in a cursive style.

Dr. Yan Peng Zhao, PRRC, Tandem Health AB