Declaration of Conformity

English

Scribe Coder Guide

Version 2.2 (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

Address:
Kungsgatan 12–14, 111 35, 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

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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, 2026-09-03

Signed on behalf of Tandem Health AB



Dr. Yan Peng Zhao, PRRC, Tandem Health AB