

 Menu

+ New chat



Declaration of Conformity

English [Scribe](#) [Coder](#) [Guide](#)

Version 1.1 (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

Address:

Malmskillnadsgatan 44a 111 57, Stockholm Sweden

Telephone number:

+46844682083

E-mail address:

support@tandemhealth.ai

Device name:

Tandem AI Medical Guide

EMDN Code:

V92, Medical Device Software – not included in other classes

MDA Code:

0315

The Tandem AI Medical Guide is a software tool intended to assist licensed healthcare professionals by processing natural language questions and inputs (queries) and generating natural language answers. It retrieves and presents clinical reference information, guidelines and treatment protocols contextually relevant to the query. The software is intended to inform clinical management by aggregating and summarising relevant clinical information and options related to the diagnosis, treatment, prevention, or mitigation of diseases and conditions. The product is not intended to provide direct diagnosis or perform calculation. All clinical decisions remain the sole responsibility of the healthcare professional, who must independently evaluate the retrieved information using their professional judgment.

Product risk classification:

Class IIa

Basic UDI-DI:

735017982TANDEMGUIDE7M

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 over a light blue horizontal line.

Dr. Yan Peng Zhao, PRRC, Tandem Health AI