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Declaration of Conformity

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Version 1.3 (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 Coder

EMDN Code:

V92, Medical Device Software – not included in other classes

MDA Code:

0315

The Coding Module (Tandem AI Medical Coder) is intended for use by healthcare professionals to support the clinical documentation process by suggesting relevant clinical codes based on the content of consultation notes. The Coding Module is intended to be used in conjunction with the Tandem AI Medical Scribe, which generates said consultation notes. The module allows users to review and select suggested codes, and to search for additional codes manually, in order to accurately document clinical findings and inform patient management. The module may also support the selection of non-clinical codes used for non-medical administrative or billing purposes. Suggested codes are not applied automatically; the healthcare professional must verify and select codes before they are transferred to the electronic health record (EHR).

Product risk classification:

Class IIa

Basic UDI-DI:

735017982TANDEMCODER53

UDI-DI:

07350179820019

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 Global Limited, declare that the product described in this Declaration conforms to the following Regulations:

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