REGULATION (EU) 2017/745 (Annex IX)

# Quality Management System Certificate

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|---|---|
| Manufacturer | **Tandem Health AB**<br><br>Malmskillnadsgatan 44a<br>11157 Stockholm<br>Sweden<br><br>SRN: SE-MF-000049463 |
| Certificate Number | **SCAR-9.2.1.5** |
| Validity | Issued: **2026-02-16**<br>Revised: **2026-06-18**<br>Expiry: **2031-02-15** |
| Device Range | **Class IIa**<br><br>• Device Category: **MDA 0315 - Software** |
| Conditions and Limitations | None |
| Conformity Assessment Procedure | The relevant conformity assessment procedure according to Regulation (EU) 2017/745, Article 52, which includes:<br><br>• conformity assessment as specified in Regulation (EU) 2017/745, Annex IX, Chapters I and III; including<br>• an assessment of the technical documentation (as specified in Regulation (EU) 2017/745, Annex IX, Section 4) of one representative device. |
| Conformity Assessment Conclusion | For the specified Device Range, Tandem Health AB has successfully demonstrated compliance according to the Conformity Assessment Procedure specified above.<br><br>This conclusion is subject to periodic surveillance, pursuant to Regulation (EU) 2017/745, Annex IX, Chapter I, Section 3. |

# Device Range

| Device Range | Device Details | Intended Purpose |
|---|---|---|
| **Class IIa - MDA 0315** | Name:<br>**Tandem AI Medical Coder (Coding Module)**<br>Basic UDI-DI:<br>**735017982TANDEMCODER53** | 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 nonmedical 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).<br>More detail in Annex A. |
| | Name:<br>**Tandem AI Medical Scribe**<br>Basic UDI-DI:<br>**735017982TANDEMSCRIBEAB** | 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.<br>More detail in Annex B. |

# Device Range

| Device Range | Device Details | Intended Purpose |
|---|---|---|
| **Class IIa - MDA 0315** | Name:<br>**Tandem AI Medical Guide (CDS Module)**<br><br>Basic UDI-DI:<br>**735017982TANDEMGUIDE7M** | 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.<br><br>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.<br><br>More detail in Annex C. |

## Certificate Version Control

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|---|---|
| SCAR-9.2.1.5 | Issued: 2026-06-18<br>Amended: Update to device name. |
| SCAR-9.2.1.4 | Issued: 2026-06-05<br>Supplemented: Addition of device, and administrative update. |
| SCAR-9.2.1.3 | Issued: 2026-05-26<br>Amended: Administrative update. |
| SCAR-9.2.1.2 | Issued: 2026-05-19<br>Supplemented: Addition of device. |
| SCAR-9.2.1.1 | Issued: 2026-04-27<br>Amended: Update to non-device data. |
| SCAR-9.2.1.0 | Issued: 2026-02-16 |



## Audit Report Reference

EUQREP-9.2.1.0

## Predetermined Change Control Plan (PCCP) Reference

PCCP-9.2.1.x

James Dewar, Director
on behalf of **Scarlet NB B.V.**

NB Number: **3022**

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# Annex A

## Device: Tandem AI Medical Coder (Coding Module)

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|---|---|
| **Indication** | For medical code documentation.<br>There is no specific medical condition associated with this device. |
| **Use environment** | In/at all settings where patient interaction occurs. |
| **Contraindication** | Not to be used on its own to diagnose or treat patients.<br>The Coding Module is intended to be used in conjunction with the Tandem AI Medical Scribe, which generates said consultation notes. |
| **Users** | The device is intended for use by certified physicians in/at all settings where patient interaction occurs. |
| **Patients** | The target patient population for the subject device is not applicable. |

# Annex B

## Device: Tandem AI Medical Scribe

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|---|---|
| **Indication** | For use by healthcare professionals to generate structured clinical documentation from patient consultations.<br><br>There is no specific medical condition associated with this device. |
| **Use environment** | In/at all settings where patient interaction occurs. |
| **Contraindication** | Not to be used on its own to diagnose or treat patients. |
| **Users** | The device is intended for use by certified healthcare professionals. |
| **Patients** | The module is intended to be used by healthcare professionals during or immediately after patient encounters. |

# Annex C

## Device: Tandem AI Medical Guide (CDS Module)

| | |
|---|---|
| **Indication** | For medical information lookup regarding care (patient management).<br><br>There is no specific medical condition associated with this device. |
| **Use environment** | In/at all settings where patient interaction occurs. |
| **Contraindication** | Not to be used on its own to diagnose or treat patients. |
| **Users** | The device is intended for use by certified healthcare professional. |
| **Patients** | The module is intended to be used by healthcare professionals during or immediately after patient encounters. There is no target patient population or specific medical condition for this device. |