EU Quality Management Certificate

This is to certify that the company

THI Total Healthcare Innovation GmbH

Gewerbestrasse 4
9181 Feistritz im Rosental
Austria

SRN: AT-MF-000044495

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	489169 MDR2017Q
Certificate ID	1000255315
Effective date	2025-07-31
Expiry date	2030-04-14
Frankfurt am Main,	2025-07-31

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Heinrich von Mettenheim
Managing Director

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of the certification can only be verified by the QR-code.

420.90 Version 7.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: AT-MF-000044495
Certificate ID: 1000255315

Device categories and variants covered by this certificate:

Device category:	**MDN1201 - Non-active non-implantable devices for anaesthesia, emergency and intensive care**
Product name:	80200 ViVi® Hood 80210 ViVi® Hood 8022x ViVi® Toga (3 sizes) 80300 ViVi® HF 80301 ViVi® HFD 80200V ViVi® Hood 8022xV ViVi® Toga (3 sizes) 80500 ViVi® Peel-Off Hood 80500V ViVi® Peel-off Hood 8023x ViVi® Pull-Over Toga (3 sizes) 8023xV ViVi® Pull-Over Toga (3 sizes) 8222x ViVi Toga Premium (4 sizes) 8222xV ViVi Toga Premium (4 sizes)
Risk classification:	Is
Basic-UDI-DI:	9009607Gown80XXXD4 9009607GOWNS82XXXDJ
Intended purpose:	The ViVi® System is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms towards the patient and the surgical personnel.

Device category:	**MDN1201 - Non-active non-implantable devices for anaesthesia, emergency and intensive care**
Product name:	SP250 Sterile Protection Shield
Risk classification:	Is
Basic-UDI-DI:	9009607SPSXXXAZ
Intended purpose:	The SP250 protection shield is a sterile component of the SPS Protection Shield System. The SPS System is intended to be worn by surgical personnel to provide a barrier between the operating environment and the surgical personnel in order to help protect against contamination and/or exposure of infectious body fluids and harmful microorganisms towards the patient and the surgical personnel.

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SRN of Manufacturer: AT-MF-000044495
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Examinations and tests performed:
AZ489169_A212387MED_01 dated 2023-10-02
AZ489169_ A212377MED_02 Protection/ViVi System dated 2025-01-25

Further conditions for or limitations to the validity of the certificate:
In case of products that are placed on the market in sterile condition, the involvement of the Notified Body in the conformity assessment procedure is limited to the aspects of manufacture concerned with securing and maintaining sterile condition.

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
01	2025-04-15	1000118699	Addition of product variants