

 Total Healthcare Innovation GmbH	<b>DECLARATION OF CONFORMITY</b> <b>ViVi® reusables</b>	MD IO 5.1_DoC_ViVi®_MDR_Class I Rev. 07                      page 1 of 2
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## DECLARATION OF CONFORMITY

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

The manufacturer declares, under its sole responsibility, that the products covered in this document are in conformance with the Medical Devices Regulations (EU) 2017/745 and with the Personal Protective Equipment Regulation (EU) 2016/425

<b>Manufacturer Name</b>	THI Total Healthcare Innovation GmbH
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System intended use: 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 to infectious body fluids and harmful microorganisms towards the patient and the surgical personnel.  The products in the table shown in Annex I are <u>accessories</u> of <b>ViVi® System</b> .	
<b>Classification</b>	Class I, Rule 11 and 13 within Annex VIII of the Regulation.
<b>Conformity Assessment Route</b>	Annex II and III
<b>Common Specifications / Standards Applied</b>	EN ISO 13485:2016 + AC 2018 + A11:2021; EN ISO 14971:2019 + A11:2021; EN ISO 20417:2021; EN ISO 15223-1:2021; IEC 60601-1:2006 + AMD1: 2012 + AMD2:2020; EN 60601-1-2:2015 +A1:2020; IEC 60601-1-6:2010 + A1:2013 + A2:2020; EN 62366-1:2015 A1:2020; Directive 2011/65 (EU - RoHS); Regulation 2023/1542 (EU battery regulation)

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Name	Karl Hintermann
Title	Quality Manager
Signature	
Place of Issuance	Feistritz im Rosental, Austria
Date	12-Sept-2025

## Annex I.

REF	Name	Variant REF	Variant name	Basic UDI-DI	Intended Use
80100	ViVi® Helmet	80100 REV-S3	ViVi Helmet Revision S3	9009607HELMET80XXXHC	The ViVi® Helmets are surgical devices that pull in and circulate fresh air throughout the helmet to aid user comfort. ViVi® Helmets are multiple-use devices, which are worn by healthcare professionals in the operating room during surgery.
		80100 REV-S4	ViVi Helmet Revision S4		
80130	ViVi® Helmet HPL	80130 REV-S3	ViVi Helmet HPL Revision S3	9009607HELMET80XXXHC	
		80130 REV-S4	ViVi Helmet HPL Revision S4		
60402	BATTERY PACK HW	-	-	9009607BATT60402WJ	This battery pack is a component of the ViVi® System, to be used by healthcare professionals to supply surgical helmets with low-voltage DC power.
60403.JP	BATTERY HOLSTER HW - JP	-	-	9009607HOLST60403WD	This battery holster is a component of the ViVi® System. Worn on the body under sterile protection gowns, it is used by healthcare personnel to connect the battery with the helmet and by doing so, to ensure a low voltage DC power supply to the helmet.
60501	SINGLE-BAY SMART CHARGER	60504	FOUR-BAY CHARGER	9009607CHARGERBLA6	This smart charger is a component of the ViVi® System, to be used by healthcare professionals outside of the patient environment to charge the Battery Pack HW REF 60402.
		60506	FOUR-BAY PRIO CHARGER		
81100	ViVi® HELMET <sup>25</sup>	81130	ViVi® HELMET <sup>25</sup> HPL (with headlight)	9009607HELMET81XXXHK	The ViVi® Helmets are surgical devices that pull in and circulate fresh air throughout the helmet to aid user comfort. ViVi® Helmets are multiple-use devices, which are worn by healthcare professionals in the operating room during surgery.
		81100XL	ViVi® HELMET <sup>25</sup> XL		
		81130XL	ViVi® HELMET <sup>25</sup> XL HPL (with headlight)		