Company: THI Total Healthcare Innovation GmbH
Address: Gewerbestraße 4
9181 Feistritz im Rosental, Austria
Phone: +43 4228 30100-0
Fax: +43 4228 30100-20
E-Mail: office@thigmbh.at
Website: www.thigmbh.at

This declaration of conformity is issued under the sole responsibility of THI Total Healthcare Innovation GmbH.

The company declares that the medical device **ViVi®**, consisting of components and accessories shown in the table in this statement is in compliance with the relevant Community harmonization legislation: **Directive 93/42/EEC**

Where applicable, compliance with essential requirements has been confirmed by: DQS Medizinprodukte GmbH, August-Schanz-Straße 21, 60433 Frankfurt am Main, Germany, Tel.: +496995427, Identification Number: 0297.

Certificate Registration No: 489169 MR2
Certificate No: 170689495

Name	REF	Use	Sterilization	Class	Rule	Annex	CE Mark
ViVi® Helmet	80100	Non sterile, reusable	-	I	1	VII	CE
ViVi® Helmet w/ Headlight	80120	Non sterile, reusable	-	I	1	VII	CE
ViVi® HOOD	80200	STERILE, single use	EO	Is	4a	II	CE0297
ViVi® HOOD	80210	STERILE, single use	EO	Is	4a	II	CE0297
ViVi® TOGA Size XL-XXL	80220	STERILE, single use	EO	Is	4a	II	CE0297
ViVi® TOGA Size M-L	80221	STERILE, single use	EO	Is	4a	II	CE0297
ViVi® TOGA Size XXS-S	80222	STERILE, single use	EO	Is	4a	II	CE0297
BATTERY PACK	60401	Non sterile, reusable	-	I	1	VII	CE
BATTERY CHARGER	60500	Non sterile, reusable	-	I	1	VII	CE
ViVi® Comfort Pads	50785	Non sterile, reusable	-	I	1	VII	CE
ViVi® Soft Pads	50786	Non sterile, reusable		I	1	VII	CE

The following harmonized standards have been used as applicable:

EN 556-1:2001/AC:2006, EN 14971:2012, EN ISO 10993-1:2009/AC:2010, EN ISO 10993-7:2008/AC:2009, EN ISO 11607-1:2009+A1:2014, EN ISO 11607-2:2006 +A1:2014, EN ISO 11135:2014, EN 13795:2001+A1:2013, EN 1041:2008+A1:2013, EN ISO 15223-1:2016 , EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 62366-1:2015 +COR1:2016, IEC 62133:2012

This declaration of conformity is valid until 2023-02-01

Issue place and date: Feistritz im Rosental, 2019-12-17

THI-Total Healthcare Innovation GmbH
Gewerbestrasse 4
A-9181 Feistritz im Rosental
Tel. +43 (0) 4228 30 100-0, Fax +43 (0) 4228 30 100-20
E-Mail: office@thigmbh.at

Dr. Giorgio Rosati
(General Manager)