



Total Healthcare Innovation GmbH

DECLARATION OF CONFORMITY

MD IO 5.1_DoC_ViVi®

Rev. 08

page 1 of 1

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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® Helmet HPL | 80130 | Non sterile, reusable | - | I | 1 | VII | CE |
| ViVi® HOOD | 80200 | STERILE, single use | EO | Is | 4a | II | CE ₀₂₉₇ |
| ViVi® HOOD | 80210 | STERILE, single use | EO | Is | 4a | II | CE ₀₂₉₇ |
| ViVi® TOGA Size XL-XXL | 80220 | STERILE, single use | EO | Is | 4a | II | CE ₀₂₉₇ |
| ViVi® TOGA Size M-L | 80221 | STERILE, single use | EO | Is | 4a | II | CE ₀₂₉₇ |
| ViVi® TOGA Size XXS-S | 80222 | STERILE, single use | EO | Is | 4a | II | CE ₀₂₉₇ |
| ViVi® HOOD HF | 80300 | STERILE, single use | EO | Is | 4a | II | CE ₀₂₉₇ |
| ViVi® HOOD HFD | 80301 | STERILE, single use | EO | Is | 4a | II | CE ₀₂₉₇ |
| BATTERY PACK | 60401 | Non sterile, reusable | - | I | 1 | VII | CE |
| BATTERY PACK HW | 60402 | | | | | | |
| BATTERY HOLSTER HW | 60403 | | | | | | |
| BATTERY CHARGER | 60500 | | | | | | |
| Single-Bay Smart Charger | 60501 | | | | | | |
| ViVi® Comfort Pads | 50785 | | | | | | |
| ViVi® Soft Pads | 50786 | | | | | | |

The following harmonized standards have been used as applicable to verify compliance with the directive:

EN 556-1:2001/AC:2006, EN 14971:2019, EN ISO 10993-1:2018, EN ISO 10993-7:2008/AC:2009, EN ISO 11607-1:2017, EN ISO 11607-2:2017, EN ISO 11135:2014/A1:2019, EN 13795-1:2019, EN 1041:2008+A1:2013, EN ISO 15223-1:2016, EN 60601-1:2006/A11:2011/ A1:2013 /A12:2014, EN 60601-1-2:2015, EN 62471:2008, IEC 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, 2020-12-07



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