

1. **PPE:** Eye and face protector / polycarbonate face-shield.



2. **Name and address of the manufacturer:**  
THI Total Healthcare Innovation GmbH  
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3. **This declaration of conformity is issued under the sole responsibility of the manufacturer.**

4. **Object of the Declaration:** Protective face-shield model **ViVi® System** consisting of the following components:

- |           |                                 |
|-----------|---------------------------------|
| REF 80100 | ViVi® HELMET                    |
| REF 80120 | ViVi® HELMET w/ HEADLIGHT       |
| REF 80200 | ViVi® HOOD                      |
| REF 80210 | ViVi® HOOD                      |
| REF 80220 | ViVi® TOGA (Size XL – XXL)      |
| REF 80221 | ViVi® TOGA (Size M – L)         |
| REF 80222 | ViVi® TOGA (Size XXS – S)       |
| REF 60401 | BATTERY PACK                    |
| REF 60500 | BATTERY CHARGER                 |
| REF 50785 | ViVi® Preplacement Comfort Pads |



Helmet + Hood = ViVi® System

Helmet + Toga = ViVi® System

5. **The object of the declaration described in point 4 is in conformity with the relevant Union harmonization legislation:** Regulation (EU) 2016/425

6. **Reference to relevant harmonized standard used including the date of the standard, in relation to which the conformity is made:** EN166:2001 “Personal eye protection – Specifications”

7. **The Notified Body** Certottica Scrl (NB 0530) Z.I. Villanova 32013 Longarone (BL) Italy **performed the EU type-examination (Module B) and issued the EU type-examination certificate N°:** AC18023 Rev.1 on 2018-10-12

8. **The PPE described in point 4 is not subject to conformity assessment procedures set out in Module D or Module C2.**

Signed for and on behalf of: THI Total Healthcare Innovation GmbH  
Place and date of issue: Feistritz, 2018-10-12  
This declaration is valid until at the latest: 2023-04-20



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Dr. Giorgio Rosati  
(General Manager)