**FERNO S.R.L.** *n. RI BO/C.F./P.IVA 01693660977 capitale sociale € 53.712,00 Società Unipersonale*

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# EU DECLARATION OF CONFORMITY

| MANUFACTURER | | |
|---|---|---|
| **Name of Company** | **Address** | **SRN / Application ID** |
| FERNO S.r.l | Via B. Zallone n.26 – 40066 Pieve di Cento (BO) - Italy | *Not yet available* / APP000027477 |

**The manufacturer declares under its own responsibility that the medical device(s):**

| PRODUCT IDENTIFICATION | | | |
|---|---|---|---|
| **Product Brand Name** | | **Photo** | |
| FERNO, B-lock | |  | |
| **EMDN** | | | |
| V08050103 - MEDICAL SUPPORT EQUIPMENT - ACCESSORIES | | | |
| **Intended Purpose** | | | |
| B-lock Head immobilizer is the medical device that ensures maximum immobilization of the neck during transport. Compatible with ScoopEXL stretcher and spinal boards. | | | |
| **REF (Item / Catalog)** | **Item Description** | **GTIN (UDI-DI)** | **GMN (Basic UDI-DI)** |
| 21-00022 | B-lock Head immobilizer | 08051380870068 | 805138087V0880HIMMK2 |

| RISK CLASS FOR MEDICAL DEVICES | |
|---|---|
| **Device Classification** | **Common Specifications** |
| Class I Rule 1 | Not applicable |

**according to:**

| HARMONIZED AND NON-HARMONIZED STANDARDS | |
|---|---|
| **Item** | **Description** |
| EN ISO 10993-17:2009 | Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002) |
| EN ISO 10993-18:2020 | Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process (ISO 10993-18:2020) |
| EN ISO 10993-5:2009 | Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009) |
| EN ISO 10993-23:2021 | Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021) |
| EN ISO 13485:2016+A11:2021 | Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) |
| EN ISO 9001:2015 | Quality management systems - Requirements (ISO 9001:2015) |

**complies with the essential requirements listed in Annex I of the Regulation (EU) 2017/745 concerning Medical Devices.**

Pieve di Cento, March 01st 2022

Signature
*Enrico Carletti - Managing Director*

This document is compiled in accordance with *Annex IV - EU declaration of conformity*

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