EC DECLARATION OF CONFORMITY

PRODUCT CATEGORY: PREMIER BED RAIL

PRODUCTS: Premier Bed Rail, Premier Plus Bed Rail, Prem-Platinum Bed Rail

PRODUCT REF': NA

CLASSIFICATION: Classified as **Class I self-declaration,** by applying **Rule No. 1** of **Annex VIII** of the **Medical Devices Regulation (MDR 2017/745)**

UDI REF: Ongoing; awaiting GS1 Agency assignment

OUR SRN REF: Awaiting EUDAMED Portal Registration

EC-REP: European Healthcare & Device Solutions Ltd.

EC-REP SRN: EI-AR-000003999

CONFORMITY ASSESSMENT ROUTE

MDR 2017/745, Article 52 (7) – Self Declaration, Annex II - Generation and Maintenance of our Technical File / Document to demonstrate compliance with the relevant General Safety & Performance Requirements (**GSPR**) of **MDR 2017/745 - Annex I.**

Parnell Products Ltd./Parnell Plus Ltd. hereby declares that the products have correct packaging and the relevant information and instructions required for the safe use of the above devices. All manufacturing activities are subjected to the appropriate methods of quality control and inspection. We declare that the above mentioned products meet the provisions of **Medical Device Regulation MDR 2017/745** relating to **medical devices** and are classified as **Class I non-surgically invasive, non-sterile self-declaration medical devices** according to **Annex VIII.** All manufacturing documentation is retained at the premises of the OEM Manufacturer. Parnell Products Ltd./Parnell Plus Ltd. QMS and Technical Documentation is **not** subject to Notified Body surveillance; however, our devices **are** registered as **Class I self-declaration products** with the HPRA (Irish Competent Authority).

NOTIFIED BODY: Not Applicable

MANUFACTURER: Parnell Products Ltd./Parnell Plus Ltd.

The Sheiling,
Nedderton Village,
Northumberland,
NE22 6AX,
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Approval: *N. Bath* Date: 16th August 2021

Nicola Bath