

We declare under our sole responsibility that the product listed below

Wir erklären in alleiniger Verantwortung, dass das unten aufgeführte Produkt
 Nous déclarons sous notre propre responsabilité que le dispositif médical

Product description, Code, Type, Model

Intended purpose

*Produktbezeichnung, Code, Typ, Modell, Zweckbestimmung
 Description du produit, code, type, modèle, destination*

Medical Bed

Medley Ergo

The bed is intended for adult users in domestic care and long-term care:

- Application environment 3: Long-term care in a medical area where medical supervision is required, and monitoring is provided, if necessary, and medical electrical equipment used in medical procedures may be provided to help maintain or improve the condition of the patient.
- Application environment 4: Care provided in a domestic area where medical electrical equipment is used to alleviate or compensate for an injury, disability or disease.

Basic UDI-DI:

5600494MEDLEYERGOYW

manufactured by:

*hergestellt durch:
 fabriqué par:*

Invacare Portugal, Lda.

Rua da Estrada Velha, 949
 4465-784 Leça do Balio
 Portugal

Single registration number (SRN)

PT-MF-000006551



Not applicable

meets all the provisions of the Regulation (EU) 2017/745 on medical devices, especially Annex I - III, which apply to it.

*allen Anforderungen der Verordnung (EU) 2017/745 über Medizinprodukte, insbesondere Anhang I - III, entspricht, die anwendbar sind.
 remplit toutes les exigences du Règlement (UE) 2017/745 relatif aux dispositifs médicaux, en particulier annexe I - III, qui le concernent.*

Device Classification according to Annex VIII Class I

*Produktklassifizierung nach Anhang VIII
 Classification selon l'annexe VIII*

*Klasse I
 Classe I*

Applied harmonised standards, common specifications, national standards or other normative documents

*Angewandte harmonisierte Normen, gemeinsame Spezifikationen nationale Normen oder andere normative Dokumente
 Normes harmonisées, spécifications communes, normes nationales et autres documents normatifs appliqués*

IEC 60601-2-52:2009+AMD1:2015
 Medical electrical equipment - Part 2-52:
 Particular requirements for the basic safety and essential performance of medical beds

Initial date of first Declaration of Conformity

28-May-2012

Erstmalige Ausstellung der Konformitätserklärung

Année de première Déclaration de Conformité

Place and issue date: Porto, 02-May-2022

Ausstellungsort und -

datum:

Lieu et date de délivrance:

Managing Director Operations

Geschäftsführer

Le Directeur des Opérations



Daniel Gonçalves