

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

Stand Assist Patient Lift

ISA™ COMPACT

ISA™ STANDARD

ISA™ PLUS

ISA™ XPLUS

The stand assist patient lift is a battery-powered transfer device and is intended to transfer and position an individual from one seating surface to another.

Basic UDI-DI:

5600494ISACZ

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

Klasse I

Classification selon l'annexe VIII

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

ISO 10535:2021, Hoists for the transfer of disabled persons - Requirements and test methods

Initial date of first Declaration of Conformity

11-Apr-2019

Erstmalige Ausstellung der Konformitätserklärung

Année de première Déclaration de Conformité

Place and issue date: Leça do Balio, 30-Jan-2025

Ausstellungsort und -datum:

Lieu et date de délivrance:

Managing Director Operations

Geschäftsführer

Le Directeur des Opérations



Daniel Gonçalves

EF-0912 – EU Declaration of Conformity

Version 12



Yes, you can.

Annex I – List of product references under this EU Declaration of Conformity

| ISA™ COMPACT | ISA™ STANDARD | ISA™ PLUS | ISA™ XPLUS |
|---------------------|----------------------|------------------|-------------------|
| 1655979 | 1655988 | 1656034 | 1655981 |
| 1655991 | 1655989 | 1656198 | 1655990 |
| 1656033 | 1656010 | 1656220 | 1656011 |
| 1656044 | 1656012 | 1660830 | 1656036 |
| 1656211 | 1656021 | 1660831 | 1656047 |
| 1660247 | 1656035 | | 1656200 |
| 1660459 | 1656045 | | 1656221 |
| 1660543 | 1656046 | | 1656239 |
| 1660829 | 1656048 | | 1660841 |
| 1660840 | 1656199 | | 1662773 |
| 1660974 | 1656212 | | 1662774 |
| 1660975 | 1656238 | | 1663641 |
| 1663379 | 1660248 | | ISAXPLUS |
| ISACOMPACT | 1660470 | | 1682403 |
| | 1660969 | | |
| | 1660970 | | |
| | 1672269 | | |