



Declaration according guideline EU 2017/745
of 5th April 2017 for medical devices.

Konformitätserklärung gem. Verordnung
EU 2017/745 vom 05.04.2017 für
Medizinprodukte

The sole responsibility for issuing this declaration
conformity lies with the manufacturer.

Die alleinige Verantwortung für die Ausstellung
dieser Konformitätserklärung liegt beim Hersteller.

| Standards/ angewendete Normen | Status | Standards/ angewendete Normen | Status |
|-------------------------------|--------|-------------------------------|--------|
| DIN EN ISO 10993-1,5,10 | 2010 | DIN EN ISO 13485 | 2016 |
| DIN EN ISO 597 part 1+2 | 2017 | DIN EN ISO 62366-1 | 2017 |
| DIN EN ISO 14971 | 2019 | MEDDEV 2.7.1 | 2016 |
| DIN EN ISO 845 | 2009 | MPDG | 2020 |
| DIN EN ISO 3386 | 2015 | MPBetreibV | 2021 |
| DIN EN ISO 16840 | 2010 | MDR | 2021 |
| DIN EN ISO 1021-1 und 1021-2 | 2014 | | |

Product/ Produkt: (class 1 / Klasse 1)

Basis UDI: +ECFM

GMDN code: 44361

Decubitus Therapy Seat Cushion / Dekubitustherapie-Sitzkissen

| Articel/Artikel | Basis UDI-DI: | Articel/Artikel | Basis UDI-DI: |
|-----------------|-----------------|-------------------|----------------|
| XSEAT® | ++ECFMXSEAT5A | XAIR® hybrid | ++ECFMXAIRHB5A |
| XSEAT® light | ++ECFMXSEATL9P | Ottobock EVOFLAIR | ++ECFMBOBEVOY2 |
| XSEAT® clinic | ++ECFMXSEATCLG9 | Ottobock LIVO | ++ECFMOBLIVO3C |
| XSEAT® advanced | ++ECFMXSEATADFK | | |
| GELSEAT® | ++ECFMGSEATXC | | |
| GELSEAT® clinic | ++ECFMGSEATCL78 | | |

Manufacturer / Hersteller:

Funke Medical GmbH
Ährenfeld 10
46348 Raesfeld
GERMANY
Single Registration Number: DE-MF-000007784

We declare herewith, that the above standing products are manufactured according to the guideline EU 2017/745 of 5th April 2017 for medical devices.

Raesfeld, 25.01.2022

Andreas Funke

1A.B2