



Declaration according guideline EU 2017/745  
of 5<sup>th</sup> 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/ies with the manufacturer.

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

Standards/ angewendete Normen	Normenstatus	Standards/ angewendete Normen	Normenstatus
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
		MDR	2021

**Product/ Produkt: (class 1 / Klasse 1)**

**Basis UDI: +ECFM**

**GMDN code: 63237**

**Decubitus Therapy Mattress/**

**Matratze zur Dekubitusprophylaxe und -therapie**

Article / Artikel	Basis UDI-DI:	Article / Artikel	Basis UDI-DI:	Article / Artikel	Basis UDI-DI:
Hyper Foam PLUS	++ECFMHFPLUSHCNL	Hyper Foam PLUS <i>clinic</i>	++ECFMHFPLUSCLNP	EVAQ®-PRO	++ECFMEQPROZ8
Hyper Foam 2	++ECFMHF2HCRM	Hyper Foam VISCO <i>clinic</i>	++ECFMHFVCLX7	EVAQ®-PRO VISCO	++ECFMEQPROV6H
MAXX 250	++ECFMMAXHC54	Hyper Foam 2 <i>clinic</i>	++ECFMHF2CLRQ	EVAQ®-PRO II	++ECFMEQPROIICF
Hyper Foam GEL	++ECFMHFGELHC2P	MAXX 250 <i>clinic</i>	++ECFMMAXCL57	EVAQ®-PRO XL	++ECFMEQPROXLE2
Hyper Foam 2 GREENLINE	++ECFMHF2HCGRTT	Hyper Foam 2 <i>clinic</i> GREENLINE	++ECFMHF2CLGRU5	MemoCareEVAQ®	++ECFMEQMC3B
Hyper AIR® <i>hybrid</i>	++ECFMHAIRHBWP	Hyper Foam PLUS <i>clinic</i> GREENLINE	++ECFMHFPLUSCLGRWR	EVAQ®-PRO II GREENLINE	++ECFMEQPROIIGRCW
Hyper Foam CC	++ECFMHFCZ8	MAXX 250 <i>clinic</i> GREENLINE	++ECFMMAXCLGRS4	EVAQ®-PRO GREENLINE	++ECFMEQPROGRCT
MemoCare	++ECFMMCL2H			EVAQ®-PRO XL GREENLINE	++ECFMEQPROXLGRGN
VISCOMED	++ECFMVISCOMEDU6				

**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 5<sup>th</sup> April 2017 for medical devices.**

Raesfeld, 25.01.2022

Andreas Funke

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