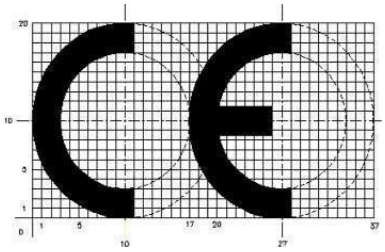

Declaration according guideline EU 2017/745 of 5th April 2017 for medical devices.

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	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 *clinic*	++ECFMHFPLUSCLNP	EVAQ®-PRO	++ECFMEQPROZ8
Hyper Foam 2	++ECFMHF2HCRM	Hyper Foam VISCO *clinic*	++ECFMHFVCLX7	EVAQ®-PRO VISCO	++ECFMEQPROV6H
MAXX 250	++ECFMMAXXHC54	Hyper Foam 2 *clinic*	++ECFMHF2CLRQ	EVAQ®-PRO II	++ECFMEQPROIICF
Hyper Foam GEL	++ECFMHFGELHC2P	MAXX 250 *clinic*	++ECFMMAXXCL57	EVAQ®-PRO XL	++ECFMEQPROXLE2
Hyper Foam 2 GREENLINE	++ECFMHF2HCGRTT	Hyper Foam 2 *clinic* GREENLINE	++ECFMHF2CLGRU5	MemoCareEVAQ®	++ECFMEQMC3B
Hyper AIR® *hybrid*	++ECFMHAIRHBWP	Hyper Foam PLUS *clinic* GREENLINE	++ECFMHFPLUSCLGRWR	EVAQ®-PRO II GREENLINE	++ECFMEQPROIIGRCW
Hyper Foam CC	++ECFMHFCCZ8	MAXX 250 *clinic* GREENLINE	++ECFMMAXXCLGRS4	EVAQ®-PRO GREENLINE	++ECFMEQPROGRCT
MemoCare	++ECFMMCCL2H			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 5th April 2017 for medical devices.

Raesfeld, 25.01.2022

Andreas Funke

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