



Konformitätserklärung *Declaration of Conformity*

Wir, die Firma

We, the company

THUASNE Deutschland GmbH
Im Steinkamp 12, D-30938 Burgwedel
Deutschland – *Germany*

SRN (Single Registration Number): DE-MF-000006210

erklären in alleiniger Verantwortung, dass unser/e Produkt/e in Anhang I

declare under our sole responsibility, that our product/s in annex I

den Anforderungen der Verordnung (EU) 2017/745 des Europäischen Parlaments und des Rates vom 05. April 2017 über Medizinprodukte entspricht/entsprechen.

Complies with the requirements of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

Unser Qualitätsmanagementsystem ist zertifiziert nach ISO 13485.

Our quality management system is certified according to ISO 13485.

Klassifizierung	Klasse I im Sinne von Anhang VIII der Verordnung (EU) 2017/745
Classification	Class I as defined in the Annex VIII of the Regulation (EU) 2017/745

Diese Erklärung gilt bis zum 06. Oktober 2023.


This declaration is valid until October 6, 2023.

Für THUASNE – *For THUASNE*

Burgwedel, 10. September 2021
Burgwedel, September 10th, 2021

DocuSigned by:

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Joachim Dehmel
Geschäftsführer
Managing Director

DocuSigned by:

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Dr. Tjark Siedentop
Leiter Forschung & Entwicklung
Director Research & Development



Anhang I zur Konformitätserklärung
vom 10. September 2021
Appendix I of Declaration of Conformity
of September 10th, 2021

Produktcode <i>Product code</i>	Produkt- oder Handelsname <i>Product name</i>	Basis UDI-DI <i>Basic UDI-DI</i>
T49100	Ortel T-Neck	4035459DE0101A2F
T49105	Ortel T-Neck Plus	4035459DE0101B2H
T49190	Cervi-moll	4035459DE0102A2J
T49200	Cervi-med	4035459DE0102B2L
T49209	Cervi-med forte	4035459DE0102C2N
T49211	PDC	4035459DE0103A2M
T49280	Ortel C4 Vario	4035459DE0104A2Q
T48040	Schulter-Fix Basic	4035459DE0201A2N
T48045	Schulter Fix Forte	4035459DE0201B2Q
T48060	Schulter-Fix Abdukt	4035459DE0201C2S
T48080	Schulter-Fix Universal	4035459DE0201D2U
T48062	Schultergurt	4035459DE0201E2W
T30080	Epi-GO	4035459DE0301A2V
T35080	Epi PROMASTER	4035459DE0301B2X
T35087	Epi-med	4035459DE0302A2Y
T48001	Epi-med	4035459DE0302B32
T30070	Manu-GO	4035459DE0401A34
T35070	Manu PROMASTER	4035459DE0401B36
T48027	Rhizo-pro	4035459DE0402A37
T49300	Orthoflex, kurz	4035459DE0403A3A



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T49310	Orthoflex, lang	4035459DE0403A3A
T30140	Lomba GO	4035459DE0501A3B
T30145	Lomba GO	4035459DE0501B3D
T35140	Reversa PROMASTER	4035459DE0501A3B
T35145	Reversa PROMASTER	4035459DE0501B3D
T54610	Lombastab Vario	4035459DE0502A3E
T54620	Lombax Vario	4035459DE0503A3H
T54640	Sleeq	4035459DE0504A3L
T54650	Sleeq SFO	4035459DE0504B3N
T54655	Sleeq SFO Plus	4035459DE0504C3Q
T54660	Sleeq Flex	4035459DE0505A3P
T54645	Separate Rückenpelotte	4035459DE0504D3S
T54646	Abdominalpelotte	4035459DE0504E3U
T54665	Verlängerungsgurt	4035459DE0504F3W
T54667	Verstärkungselement	4035459DE0504G3Y
T54753	Reversa Vario PROMASTER Damen	4035459DE0506A3S
T54752	Reversa Vario PROMASTER Damen	4035459DE0506A3S
T54793	Reversa Vario PROMASTER Herren	4035459DE0506B3U
T54794	Reversa Vario PROMASTER Herren	4035459DE0506B3U
T54795	Reversa Vario PROMASTER Herren	4035459DE0506B3U
T54756	Reversa Vario Plus PROMASTER	4035459DE0507A3V
T54796	Reversa Vario Plus PROMASTER	4035459DE0507B3X
T54850	Osteo-med Damen	4035459DE0508A3Y
T54854	Osteo-med Damen S	4035459DE0508B42
T54880	Osteomed Acute	4035459DE0509A43



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T64050	Überbrückungspelotte	4035459DE0601A3J
T64079	Flex-Pelotte	4035459DE0601A3J
67838	Kreuz-Lendenpelotte	4035459DE0601A3J
67841	Soft-Pelotte	4035459DE0601A3J
T51550	Hip-med	4035459DE0701A3R
T54050	HipLoc Evo	4035459DE0702A3U
T30040	Genu-GO	4035459DE0801A3Y
T35040	Genu PROMASTER	4035459DE0801B42
T35043	Genu FS	4035459DE0802A43
T35045	Genu PFS PROMASTER	4035459DE0802B45
T35047	Genu OA	4035459DE0803A46
T39100	GenuPro Control	4035459DE0804A49
T30020	Malleo GO	4035459DE0901A47
T35020	Malleo PROMASTER	4035459DE0901B49
T35022	Malleo PROMASTER Aktiv	4035459DE0901C4B
T47965	Pero-med AFO III / II	4035459DE0902A4A
T47972	Pero-med	4035459DE0902B4C
T47973	Malleo Dynastab Vario	4035459DE0903A4D
U01703	Sprystep	4035459DE0904A4G
U0171	Sprystep Flex	4035459DE0904B4J
U0172	Sprystep Plus	4035459DE0904C4L
U0173	Sprystep Max	4035459DE0904D4N
U0175	Sprystep Pediatric Sprystep Paediatric (UK spelling)	4035459DE0904E4Q
T50030	Podo-med	4035459DE1001A2K



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T50031	Podo-med	4035459DE1001A2K
T50040	Podo-med	4035459DE1001A2K
T50045	Podo-med	4035459DE1001A2K
T50047	Podo-med	4035459DE1001A2K
T50050	Podo-med	4035459DE1001A2K
T50051	Podo-med	4035459DE1001A2K
T50035	Bügel	4035459DE1001B2M
T50037	Schutzkappe	4035459DE1001C2P
T50046	Sohle	4035459DE1001D2R
T47980	Elastocalx N	4035459DE1101A2S
T47981	Elastocalx S/P	4035459DE1101A2S
T47982	Elastocalx Plus	4035459DE1101A2S
T47991	Elastocalx Flex	4035459DE1101A2S
T47880	Podosil	4035459DE1102A2V
T47984	Sohli	4035459DE1103A2Y