

KONFORMITÄTSERKLÄRUNG / DECLARATION DE CONFORMITE
DECLARATION OF CONFORMITY / DICHIARIZIONE DI CONFORMITA

Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que /
Dichiariamo sotto nostra responsabilità che / We declare under our sole responsibility that

die Medizinprodukte
les dispositifs médicaux
the medical devices
i dispositivi medici

VENOSAN® 8000 ULCERFIT

der Klasse/ de la classe/ di classe/ of class

I (one)

Nach Anhang VIII der Verordnung EU MDR 2017/745
selon l'annexe VIII du règlement RMD 2017/745 de l'UE
secondo l'allegato VIII del regolamento UE MDR 2017/745
according to Annex VIII of Regulation EU MDR 2017/745

allen Anforderungen der Medizinprodukte-Verordnung EU MDR 2017/745 entsprechen
remplit toutes les exigences de la directive sur les dispositifs médicaux RMD 2017/745 de l'UE qui le concernent
soddisfa tutte le disposizioni della direttiva UE MDR 2017/745 ehe lo riguardano
meet all the provisions of the directive EU MDR 2017/745 which apply to it.

Konformitätsbewertungsverfahren
Procédure d'évaluation de la conformité
Procedimento di valutazione della conformità
Conformity assessment procedure

Anhang IX
Annexe IX
Allegato IX
Annex IX

St. Gallen, 06.05.2021



Danilo Pieri
Managing Director



Matea Hrzic
Product Manager

List of REFs

For all REFs **GMDN: 42811**

REF	Description	UDI-DI (GTIN-13)
SG80001	V8000 ULCERFIT 10 mm Hg OTS AD white small closed toe	7640181157235
SG80002	V8000 ULCERFIT 10 mm Hg OTS AD white medium closed toe	7640181157242
SG80003	V8000 ULCERFIT 10 mm Hg OTS AD white large closed toe	7640181157259
SG80004	V8000 ULCERFIT 10 mm Hg OTS AD white X-large closed toe	7640181157266
SG82001	V8000 ULCERFIT Ccl. 2 OTS AD small long	7640181157273
SG82002	V8000 ULCERFIT Ccl. 2 OTS AD medium long	7640181157280
SG82003	V8000 ULCERFIT Ccl. 2 OTS AD large long	7640181157297
SG82004	V8000 ULCERFIT Ccl. 2 OTS AD X-large long	7640181157303
SG82021	V8000 ULCERFIT Ccl. 2 OTS AD small short	7640181157310
SG82022	V8000 ULCERFIT Ccl. 2 OTS AD medium short	7640181157327
SG82023	V8000 ULCERFIT Ccl. 2 OTS AD large short	7640181157334
SG82024	V8000 ULCERFIT Ccl. 2 OTS AD X-large short	7640181157341
SG83001	V8000 ULCERFIT Ccl. 3 OTS AD small long	7640181157358
SG83002	V8000 ULCERFIT Ccl. 3 OTS AD medium long	7640181157365
SG83003	V8000 ULCERFIT Ccl. 3 OTS AD large long	7640181157372
SG83004	V8000 ULCERFIT Ccl. 3 OTS AD X-large long	7640181157389
SG83021	V8000 ULCERFIT Ccl. 3 OTS AD small short	7640181157396
SG83022	V8000 ULCERFIT Ccl. 3 OTS AD medium short	7640181157402
SG83023	V8000 ULCERFIT Ccl. 3 OTS AD large short	7640181157419
SG83024	V8000 ULCERFIT Ccl. 3 OTS AD X-large short	7640181157426