

Konformitätserklärung / Declaration de la Confirmation / Dichiarazione di Conformità / Declaración de conformidad / Declaration of conformity

Name und Adresse der Firma	ultraMEDIC GmbH
Nom et adresse de l'entreprise	Im Bruch 11 - 15
Nome e indirizzo della ditta	56567 Neuwied
Nombre y dirección de la empresa	Germany
Name and address of the company	SRN: DE-MF-000006242

Wir erklären in alleiniger Verantwortung, dass / Nous déclarons sous notre propre responsabilité que /
Dichiariamo sotto la nostra esclusiva responsabilità che / Declaramos bajo nuestra única responsabilidad que /
We declare our sole responsibility that

dass die Medizinprodukte gemäß nachfolgender Anlage
que les dispositifs médicaux sont fabriqués conformément à l'annexe suivante
che i dispositivi medici siano fabbricati in conformità al seguente allegato
que los productos sanitarios se fabriquen de conformidad con el siguiente anexo
that the medical devices according to the following Appendix

der Klasse / de la classe / in classe
de clase / of class

I

*Nach Anhang VIII der Verordnung (EU) 2017/745 / selon l'annexe VIII la Règlement (EU) 2017/745
secondo l'allegato VIII Regolamento (UE) 2017/745 / Según el Anexo VIII del Reglamento (UE) 2017/745
according to annex VIII of Regulation (EU) 2017/745*

allen Anforderungen der Verordnung (EU) 2017/745 entsprechen, die anwendbar sind.
remplit toutes les exigences sur les Règlement (EU) 2017/745, qui le concernent.
è conforme a tutti i requisiti del Regolamento (UE) 2017/745, applicabile.
cumple con todos los requisitos del Reglamento (UE) 2017/745, que son aplicables.
meets all the provisions of the Regulation (EU) 2017/745, which apply to it.

Angewandte harmonisierte Normen, nationale Normen
oder andere normative Dokumente.
Normes harmonisées, normes nationales et autres documents
normatifs appliqués.
Norme armonizzate applicate, norme nazionali o altri
documenti normativi.
Normas armonizadas aplicadas, normas nacionales
u otros documentos normativos.
Applied harmonized standards, national standards or other
normative documents.

EN ISO 10993-5
EN ISO 14971
EN ISO 15223-1
DIN 13024-1 (gilt für ultraSTRETCHER 0350)
DIN 13024-2 (gilt für ultraSTRETECHER 0710)
DIN EN 1865-1 (gilt für Schaufeltragen)

Gültig von / Valable à partir de / Valido da / Válido desde / Valid from: 11.09.2024
Gültig bis / Valable jusqu'au / Valido fino al / Válido hasta / Valid until: 10.09.2029

Neuwied, 11.09.2024



i.A. Daniel Weber
Ltg. Regulatory Affairs

ANLAGE

Artikel	Bezeichnung	Basis-UDI	GTIN
SAN-0143-BE	ultraCLAP 300	42518243000001FY	4251824301415
SAN-0143-BOR	ultraCLAP 300	42518243000001FY	4251824301422
SAN-0143-DBL	ultraCLAP 300	42518243000001FY	4251824301439
SAN-0143-DGR	ultraCLAP 300	42518243000001FY	4251824301446
SAN-0143-GE	ultraCLAP 300	42518243000001FY	4251824301453
SAN-0143-HGR	ultraCLAP 300	42518243000001FY	4251824301460
SAN-0143-MBL	ultraCLAP 300	42518243000001FY	4251824301477
SAN-0143-MBR	ultraCLAP 300	42518243000001FY	4251824301484
SAN-0143-ME	ultraCLAP 300	42518243000001FY	4251824301491
SAN-0143-RO	ultraCLAP 300	42518243000001FY	4251824301507
SAN-0143-SA	ultraCLAP 300	42518243000001FY	4251824301514
SAN-0143-SW	ultraCLAP 300	42518243000001FY	4251824301521
SAN-0143-TGR	ultraCLAP 300	42518243000001FY	4251824301538
SAN-0143-WE	ultraCLAP 300	42518243000001FY	4251824301545
SAN-0146-BE	ultraCLAP 200	42518243000001FY	4251824301552
SAN-0146-BOR	ultraCLAP 200	42518243000001FY	4251824301569
SAN-0146-DBL	ultraCLAP 200	42518243000001FY	4251824301576
SAN-0146-DGR	ultraCLAP 200	42518243000001FY	4251824301583
SAN-0146-GE	ultraCLAP 200	42518243000001FY	4251824301590
SAN-0146-HGR	ultraCLAP 200	42518243000001FY	4251824301606
SAN-0146-MBL	ultraCLAP 200	42518243000001FY	4251824301613
SAN-0146-MBR	ultraCLAP 200	42518243000001FY	4251824301620
SAN-0146-ME	ultraCLAP 200	42518243000001FY	4251824301637
SAN-0146-PET	ultraCLAP 200	42518243000001FY	4251824301644
SAN-0146-RO	ultraCLAP 200	42518243000001FY	4251824301651
SAN-0146-SA	ultraCLAP 200	42518243000001FY	4251824301668
SAN-0146-SW	ultraCLAP 200	42518243000001FY	4251824301675
SAN-0146-TGR	ultraCLAP 200	42518243000001FY	4251824301682
SAN-0146-WE	ultraCLAP 200	42518243000001FY	4251824301699
SAN-0146-SW-H	ultraCLAP 200	42518243000001FY	4251824307493
SAN-0147-BE	ultraREST "200"	42518243000001FY	4251824301705
SAN-0147-BOR	ultraREST "200"	42518243000001FY	4251824301712
SAN-0147-DBL	ultraREST "200"	42518243000001FY	4251824301729
SAN-0147-DGR	ultraREST "200"	42518243000001FY	4251824301736
SAN-0147-GE	ultraREST "200"	42518243000001FY	4251824301743
SAN-0147-HGR	ultraREST "200"	42518243000001FY	4251824301750
SAN-0147-MBL	ultraREST "200"	42518243000001FY	4251824301767
SAN-0147-MBR	ultraREST "200"	42518243000001FY	4251824301774
SAN-0147-ME	ultraREST "200"	42518243000001FY	4251824301781
SAN-0147-PET	ultraREST "200"	42518243000001FY	4251824301798
SAN-0147-RO	ultraREST "200"	42518243000001FY	4251824301804
SAN-0147-SA	ultraREST "200"	42518243000001FY	4251824301811
SAN-0147-SW	ultraREST "200"	42518243000001FY	4251824301828
SAN-0147-TGR	ultraREST "200"	42518243000001FY	4251824301835
SAN-0147-WE	ultraREST "200"	42518243000001FY	4251824301842
SAN-0147-SW-H	ultraREST "200"	42518243000001FY	4251824307509
SAN-0150-BE	ultraREST "300"	42518243000001FY	4251824301859
SAN-0150-BOR	ultraREST "300"	42518243000001FY	4251824301866
SAN-0150-DBL	ultraREST "300"	42518243000001FY	4251824301873
SAN-0150-DGR	ultraREST "300"	42518243000001FY	4251824301880
SAN-0150-GE	ultraREST "300"	42518243000001FY	4251824301897
SAN-0150-HGR	ultraREST "300"	42518243000001FY	4251824301903
SAN-0150-MBL	ultraREST "300"	42518243000001FY	4251824301910

Artikel	Bezeichnung	Basis-UDI	GTIN
SAN-0150-MBR	ultraREST "300"	42518243000001FY	4251824301927
SAN-0150-ME	ultraREST "300"	42518243000001FY	4251824301934
SAN-0150-PET	ultraREST "300"	42518243000001FY	4251824301941
SAN-0150-RO	ultraREST "300"	42518243000001FY	4251824301958
SAN-0150-SA	ultraREST "300"	42518243000001FY	4251824301965
SAN-0150-SW	ultraREST "300"	42518243000001FY	4251824301972
SAN-0150-TGR	ultraREST "300"	42518243000001FY	4251824301989
SAN-0150-WE	ultraREST "300"	42518243000001FY	4251824301996
SAN-0153-BE	ultraCHECK "200"	42518243000001FY	4251824302009
SAN-0153-BOR	ultraCHECK "200"	42518243000001FY	4251824302016
SAN-0153-DBL	ultraCHECK "200"	42518243000001FY	4251824302023
SAN-0153-DGR	ultraCHECK "200"	42518243000001FY	4251824302030
SAN-0153-GE	ultraCHECK "200"	42518243000001FY	4251824302047
SAN-0153-HGR	ultraCHECK "200"	42518243000001FY	4251824302054
SAN-0153-MBL	ultraCHECK "200"	42518243000001FY	4251824302061
SAN-0153-MBR	ultraCHECK "200"	42518243000001FY	4251824302078
SAN-0153-ME	ultraCHECK "200"	42518243000001FY	4251824302085
SAN-0153-PET	ultraCHECK "200"	42518243000001FY	4251824302092
SAN-0153-RO	ultraCHECK "200"	42518243000001FY	4251824302108
SAN-0153-SA	ultraCHECK "200"	42518243000001FY	4251824302115
SAN-0153-SW	ultraCHECK "200"	42518243000001FY	4251824302122
SAN-0153-TGR	ultraCHECK "200"	42518243000001FY	4251824302139
SAN-0153-WE	ultraCHECK "200"	42518243000001FY	4251824302146
SAN-0153-SW	ultraCHECK "200"	42518243000001FY	4251824307516
SAN-0155-BE	ultraCHECK "300"	42518243000001FY	4251824302153
SAN-0155-BOR	ultraCHECK "300"	42518243000001FY	4251824302160
SAN-0155-DBL	ultraCHECK "300"	42518243000001FY	4251824302177
SAN-0155-DGR	ultraCHECK "300"	42518243000001FY	4251824302184
SAN-0155-GE	ultraCHECK "300"	42518243000001FY	4251824302191
SAN-0155-HGR	ultraCHECK "300"	42518243000001FY	4251824302207
SAN-0155-MBL	ultraCHECK "300"	42518243000001FY	4251824302214
SAN-0155-MBR	ultraCHECK "300"	42518243000001FY	4251824302221
SAN-0155-ME	ultraCHECK "300"	42518243000001FY	4251824302238
SAN-0155-PET	ultraCHECK "300"	42518243000001FY	4251824302245
SAN-0155-RO	ultraCHECK "300"	42518243000001FY	4251824302252
SAN-0155-SA	ultraCHECK "300"	42518243000001FY	4251824302269
SAN-0155-SW	ultraCHECK "300"	42518243000001FY	4251824302276
SAN-0155-TGR	ultraCHECK "300"	42518243000001FY	4251824302283
SAN-0155-WE	ultraCHECK "300"	42518243000001FY	4251824302290
SAN-0101-2G2R	ultraSTRETCHER "0350"	42518243000002G2	4251824302306
SAN-0101-4G	ultraSTRETCHER "0350"	42518243000002G2	4251824302313
SAN-0101-4R	ultraSTRETCHER "0350"	42518243000002G2	4251824302320
SAN-0104-2G2R	ultraSTRETCHER "0710"	42518243000002G2	4251824302337
SAN-0104-4G	ultraSTRETCHER "0710"	42518243000002G2	4251824302344
SAN-0104-4R	ultraSTRETCHER "0710"	42518243000002G2	4251824302351
SAN-0134	ultraROLLER II	42518243000005G8	4251824302368
SAN-0135	ultraROLLER I	42518243000005G8	4251824302375
SAN-3101-2G2R	ultraSTRETCHER "0350 M"	42518243000002G2	4251824302382
SAN-3101-4G	ultraSTRETCHER "0350 M"	42518243000002G2	4251824302399
SAN-3101-4R	ultraSTRETCHER "0350 M"	42518243000002G2	4251824302405
SAN-3104-2G2R	ultraSTRETCHER "0710 M"	42518243000002G2	4251824302412
SAN-3104-4G	ultraSTRETCHER "0710 M"	42518243000002G2	4251824302429
SAN-3104-4R	ultraSTRETCHER "0710 M"	42518243000002G2	4251824302436
SAN-3106-4G	ultraCOMPACT STRETCHER	42518243000002G2	4251824302443
SAN-R0104-4G	ultraSTRETCHER "0710 R"	42518243000002G2	4251824302450

Artikel	Bezeichnung	Basis-UDI	GTIN
SAN-R0101-4G	ultraSTRETCHER "0350 R"	42518243000002G2	4251824305840
SAN-R0101-2G2R	ultraSTRETCHER "0350 R"	42518243000002G2	4251824306519
SAN-0037	ultraRESC SEAT	42518243000005G8	4251824304539
SAN-0038	ultraSEAT	42518243000005G8	4251824304522
SAN-0086	ultraBRIDLES	42518243000003G4	4251824302498
SAN-0087-1	ultraBASKET STRETCHER	42518243000002G2	4251824302504
SAN-0087-1-M	ultraBASKET STRETCHER	42518243000002G2	4251824302511
SAN-0087-2	ultraBASKET STRETCHER "TWIN"	42518243000002G2	4251824302528
SAN-0087-2-XXL	ultraBASKET STRETCHER XXL	42518243000002G2	4251824302535
SAN-0090	ultraMINING	42518243000002G2	4251824302580
SAN-0093	ultraMINING+	42518243000002G2	4251824304348
SAN-0125	ultraSCOOP STRETCHER	42518243000002G2	4251824302610
SAN-0159	ultraSAVER	42518243000002G2	4251824302634
SAN-0284	ultraHEAD-LOCK I	42518243000004G6	4251824302665
SAN-0285	ultraHEAD-LOCK II	42518243000004G6	4251824302672
SAN-0288	ultraSCOOP STRETCHER "X-RAY"	42518243000002G2	4251824302696
SAN-0288-SCX	ultraSCOOP STRETCHER X-RAY	42518243000002G2	4251824302702
SAN-0294	S-BOON	42518243000002G2	4251824302719
SAN-0294-S2	S-BOON Set II	42518243000002G2	4251824302726
SAN-0295	S-BOON	42518243000002G2	4251824302733
SAN-0295-S1	S-BOON Set I	42518243000002G2	4251824302740
SAN-0296	ultraCOMBI-STRETCHER	42518243000002G2	4251824302757
SAN-0297	ultraSCOOP STRETCHER CARBON	42518243000002G2	4251824306816
SAN-0400	ultraSTAND	42518243000005G8	4251824304560
SAN-0555	ultraSAVER	42518243000002G2	4251824302764
SAN-0556	ultraSAVER "SPEZIAL"	42518243000002G2	4251824302771
SAN-0557	ultraSAVER"SPEZIAL"	42518243000002G2	4251824302788
SAN-0558	ultraSAVER"SPEZIAL-XXL"	42518243000002G2	4251824302795
SAN-0559	ultraSAVER EVAC	42518243000002G2	4251824302801
SAN-0559-CARE	ultraSAVER EVAC CARELINE	42518243000002G2	4251824302818
SAN-8020	ultraRESCUE BOARD	42518243000005G8	4251824302825
SAN-9201	ultraRESCUE CHAIR	42518243000005G8	4251824306496
SAN-9202	ultraRESCUE CHAIR STAIR	42518243000005G8	4251824306502
SAN-9005-H	ultraFIX-HORIZINTAL	42518243000003G4	4251824302863
SAN-9005-V	ultraFIX-VERTICAL	42518243000003G4	4251824302870
SAN-0097-P	ultraFLEX PRO	42518243000003G4	4251824307417