

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 proper 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 XIII der Verordnung (EU) 2017/745 / selon l'annexe XIII la Règlement (EU) 2017/745
secondo l'allegato XIII Regolamento (UE) 2017/745 / Según el Anexo XIII del Reglamento (UE) 2017/745
according to annex XIII 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

Gültig von / Valable à partir de / Valido da / Válido desde / Valid from: 14.05.2021
Gültig bis / Valable jusqu'au / Valido fino al / Válido hasta / Valid until: 13.05.2026

Neuwied, 14.05.2021



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-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-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 |
| SAN-0150-MBR | ultraREST "300" | 42518243000001FY | 4251824301927 |
| SAN-0150-ME | ultraREST "300" | 42518243000001FY | 4251824301934 |

| Artikel | Bezeichnung | Basis-UDI | GTIN |
|----------------|-------------------------|------------------|---------------|
| 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-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 |
| SAN-R0101-4G | ultraSTRETCHER "0350 R" | 42518243000002G2 | 4251824305840 |
| SAN-R0101-2G2R | ultraSTRETCHER "0350 R" | 42518243000002G2 | 4251824306519 |
| SAN-0037 | ultraRESC SEAT | 42518243000005G8 | 4251824304539 |

| Artikel | Bezeichnung | Basis-UDI | GTIN |
|----------------|------------------------------|------------------|---------------|
| 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-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 mit Raupe | 42518243000005G8 | 4251824306502 |