

We

## Schnitzler Rettungsprodukte GmbH & Co. KG

Rudolf-Diesel-Str.:7 - 53859 Niederkassel Manufacturer SRN: DE-MF000005349

declare under their sole responsibility, that the Class I medical devices listed below (non-sterile and without measuring function) according to MDR Annex VIII, Rule 1 with the intended purpose as:

### Stretcher mattress - Positioning patients on a stretcher during transport and secure

with the basic UDI-DI: 426038867LagerungJR / 426038867GurtsystemeNZ

comply with the relevant provisions of the EU Medical Device Regulation (EU) 2017/745 and, where applicable, other relevant Union legislation

| The product group for the stretcher type 3002; 3003; 3006; 3008 of the manufacturer Stollenwerk includes the following products: |              |                                                                                                     |              |
|----------------------------------------------------------------------------------------------------------------------------------|--------------|-----------------------------------------------------------------------------------------------------|--------------|
| Trade name:                                                                                                                      | Article Nr.: | Trade name:                                                                                         | Article Nr.: |
| Tragenauflage, m. integrierten Automatik-Schultergurten und mit integr. Baby u. Kinder-Rückhaltesystem                           | 001-02       | Tragenauflage, m. integrierten Automatik-Schultergurten ohne integr. Baby u. Kinder Rückhaltesystem | 001          |
| Tragenauflage ECO, mit integr. Baby u. Kinder-Rückhaltesystem                                                                    | 1-02-02      | Tragenauflage ECO, ohne integr. Baby u. Kinder-Rückhaltesystem                                      | 1-02-00      |
| Tragenauflage KOMFORT, mit integriertem Baby- u. Kinder-Rückhaltesystem                                                          | 1-01-02      | Tragenauflage KOMFORT, ohne integriertem Baby- u. Kinder-Rückhaltesystem                            | 1-01-00      |
| Automatik-Statik-Rückhaltesystem gem. EN 1789                                                                                    | 1-418-XXX    | Statik-Rückhaltesystem gem. EN 1789                                                                 | 1-410-XXX    |
| Automatik-Statik Rückhaltesystem Hygiene+                                                                                        | 1-418-H+-XX  | Statik-Rückhaltesystem Hygiene+                                                                     | 1-410-H+-XX  |
| Fußseitige Auffangsicherung gem. EN 1789                                                                                         | S412         | Kopfteilverlängerung nach DIN 1789                                                                  | S411         |
| The product group for the stretcher type CPS of the manufacturer Stollenwerk includes the following products:                    |              |                                                                                                     |              |
| Tragenauflage KOMFORT, mit integriertem Baby- u. Kinder-Rückhaltesystem                                                          | 8-01-02      | Tragenauflage KOMFORT, ohne integriertem Baby- u. Kinder-Rückhaltesystem                            | 8-01-00      |
| Statik-Rückhaltesystem gem. EN 1789                                                                                              | 8-410-H+XX   |                                                                                                     |              |

- The conformity assessment procedure referred to in Article 19 and Annex IV has been carried out. The technical documentation is prepared in accordance with Annexes II and III. With this EU Declaration of Conformity, we, as a manufacturer of medical devices, declare that Class I, compliance without the involvement of a notified body in accordance with MDR Article 52, Paragraph(7)
- Applicable harmonized standards, national standards or other regulatory documents:
  - EN ISO 13485 - Medical devices - Quality management systems
  - EN ISO 14971 - Application of risk management to medical devices
  - EN 1865-1 - Ambulance transport equipment
- Authorized representative:
  - [CH] Ambu-Tech AG, Lettenstraße: 6c, 6343 Rotkreuz, Reg. Nr: CHRN-AR-20002714