



**Declaration of conformity to EU Medical Device Regulation  
2017/745  
FB V7.3.02-04-6**

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<b>Legal Manufacturer</b>	Tracoe Medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm Germany SRN: DE-MF-000006938
<b>EU Product Classification according to Annex VIII</b>	I Rule Number: 1
<b>Intended Purpose</b>	Tracoe care Neck Straps are used to secure the tracheostomy tube neck plate on the patient. They assist by keeping the device in position and prevent it from coming out of the tracheostoma.
<b>Basic UDI-DI</b>	4035324NECK_STRAPSP9
<b>Conformity to Common Specification(s)</b>	No relevant Common Specification to list
<b>Conformity to other Union Legislation(s)</b>	No relevant Union Legislation to list

This EU Declaration of Conformity is issued under the sole responsibility of Tracoe Medical GmbH. Tracoe Medical GmbH declares that the devices covered by the present declaration are in conformity with the Regulation (EU) 2017/745 of the European Parliament and Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled.

Date of signature: 2024-05-08  
yyyy-mm-dd

Place of signature: Nieder-Olm, Germany  
Place, Country

Signed on behalf of Tracoe Medical GmbH:

  
Dr. Hans-Marcus Kränzler, Managing Director  
Name, Title

This EU Declaration of conformity is applicable for following catalogue numbers:

Catalogue Number	Product Name	UDI-DI	Original CE Marking Date yyyy-mm-dd
REF 903-B	Tracoe care Neck Strap	04035324046911	1995-02-01
REF 903-B-P	Tracoe care Neck Strap	04035324014903	1995-02-01
REF 903-D	Tracoe care Neck Strap	04035324047116	1995-02-01
REF 903-E	Tracoe care Neck Strap	04035324047215	1995-02-01
REF 903-E-P	Tracoe care Neck Strap	04035324017775	1995-02-01
REF 903-F	Tracoe care Neck Strap	04035324064014	1995-02-01
REF 903-F-P	Tracoe care Neck Strap	04035324015030	1995-02-01
REF 903-G	Tracoe care Neck Strap	04035324012121	1995-02-01