

Legal Manufacturer	Tracoe Medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm Germany SRN: DE-MF-000006938	EU Product Classification according to Annex VIII	I Rule Number: 1	Intended Purpose	The Tracoe care Cleaning Products are designed to clean single use tracheostomy tubes while they are in use for an individual patient. The Tracoe care Cleaning Cloth is for daily cleaning and care of the skin around the tracheostoma. Tracoe Paraffin oil is indicated to lubricate the inner cannula of Tracoe Comfort tracheostomy tubes before insertion into the corresponding outer cannula.	Basic UDI-DI	Cleaning products: 4035324CLEANINGKS REF 970: 4035324CLEANING_CLOTHUU REF 902: 4035324PARAFFIN_OIL6B	Conformity to Common Specification(s)	No relevant Common Specification to list	Conformity to other Union Legislation(s)	No relevant Union Legislation to list
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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) 2021/7745 of the European Parliament and Council of 5 April 2017 on medical devices and the requirements specified herein are fulfilled.

Date of signature:

2025-09-10

yyyy-mm-dd

Place of signature:

Nieder-Olm, Germany

Place, Country

Signed on behalf of Tracoe Medical GmbH:



Felix Dreher, Head of Product Lifecycle Management Global

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 902	Tracoe care Paraffin oil	04035324046713	1999-10-01
REF 932	Tracoe tube clean Cleaning Powder	04035324060917	2001-05-01
REF 934	Tracoe tube clean cleaning tub	04035324061112	2001-05-01
REF 970	Tracoe care Cleaning Cloth	04035324011766	2002-10-01