Legal Manufacturer	Tracoe Medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm Germany SRN: DE-MF-000006938
EU Product Classification according to Annex VIII	IIa Rule Number: Dilation Set: Rule 6 / Seldinger Guide Wires: Rule 5
Intended Purpose	The Tracoe Experc Dilation Set (REF 520) is intended for performing a percutaneous dilation tracheostomy, applying the Ciaglia technique with a Seldinger guide wire. The Tracoe Seldinger Guide Wire with Guiding Catheter (REF 517) facilitates the reinsertion when changing the Tracoe Twist Tracheostomy Tubes with minimally traumatic inserter. The Tracoe Seldinger Guide Wire (REF 518) facilitates the reinsertion when changing Tracoe Twist Plus tracheostomy tubes with minimally traumatic insertion system, Tracoe Vario tracheostomy tubes with minimally traumatic insertion system, and all Tracoe tracheostomy tubes with perforated obturator.
Basic UDI-DI	Dilation Set: 4035324EXPERC_DIL_SET46 REF 517: 4035324REF517FB REF 518: 4035324REF518FD
Conformity Assessment Procedure	Annex IX
Notified Body Name and Number	TÜV Süd Product Service GmbH (0123)
Notified Body Certificate Type and Number	EU Quality Management System Certificate G10 036993 0025
Conformity to Common Specification(s)	No relevant Common Specification to list
Conformity to other Union Legislation(s)	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) 20217/745 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 520	Tracoe Experc Dilation Set	04035324017263	2006-12-01
REF 517	Tracoe Seldinger Guide Wire with Guiding Catheter	04035324016310	2006-12-01
REF 518	Tracoe Seldinger Guide Wire	04035324016860	2006-12-01