

Legal Manufacturer	Tracoe Medical GmbH Reichelsheimer Str. 1/3 55268 Nieder-Olm Germany SRN: DE-MF-000006938
EU Product Classification according to Annex VIII	IIb Rule Number: 5
Intended Purpose	Tracoe Twist Plus tracheostomy tubes are indicated for providing tracheal access for airway management. They may be used up to 29 days. Tracoe Twist Plus spare inner cannulas are indicated for use only in combination with Tracoe Twist Plus tracheostomy tube. They may be used up to 29 days. The product is intended to be used only in combination with Tracoe Twist Plus outer cannulas of the corresponding size. For the application refer to the instructions for use for the Tracoe Twist Plus tracheostomy tubes. For information on Clinical Benefit, Patient Population, Clinical Use, Intended User and Indications for Use please refer to the instructions for use of the respective Tracoe Twist Plus tracheostomy tube. Tracoe Experc set Twist Plus: Tracoe Experc Dilatation Set for percutaneous tracheostomy is intended for performing a percutaneous dilation tracheotomy, applying the Ciaglia technique with a Seldinger guide wire. Tracoe Twist Plus tracheostomy tubes are indicated for providing tracheal access for airway management. They may be used up to 29 days.
Basic UDI-DI	Twist Plus tracheostomy tubes with(out) minimally traumatic insertion system: 4035324TWIST_PLUSSR Twist Plus spare inner cannulas: 4035324SPARE_TWIST_PLUS33 Twist Plus Experc Sets: 4035324EXPERC_TWISTPLUSP7
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) 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:

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
311-07	Tracoe Twist Plus tracheostomy tube with low pressure cuff	04035324017942	2010-01-01
311-08	Tracoe Twist Plus tracheostomy tube with low pressure cuff	04035324017959	2010-01-01
311-09	Tracoe Twist Plus tracheostomy tube with low pressure cuff	04035324017966	2010-01-01
311-10	Tracoe Twist Plus tracheostomy tube with low pressure cuff	04035324017973	2010-01-01
311-07-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter and low pressure cuff	04035324018369	2010-01-01
311-08-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter and low pressure cuff	04035324018376	2010-01-01
311-09-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter and low pressure cuff	04035324018383	2010-01-01
311-10-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter and low pressure cuff	04035324018390	2010-01-01
312-07	Tracoe Twist Plus tracheostomy tube with low pressure cuff and double fenestration at inner and outer bend	04035324017980	2010-01-01
312-08	Tracoe Twist Plus tracheostomy tube with low pressure cuff and double fenestration at inner and outer bend	04035324017997	2010-01-01
312-09	Tracoe Twist Plus tracheostomy tube with low pressure cuff and double fenestration at inner and outer bend	04035324018000	2010-01-01
312-10	Tracoe Twist Plus tracheostomy tube with low pressure cuff and double fenestration at inner and outer bend	04035324018024	2010-01-01
312-07-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff and double fenestration at inner and outer bend	04035324018406	2010-01-01
312-08-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff and double fenestration at inner and outer bend	04035324018420	2010-01-01
312-09-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff and double fenestration at inner and outer bend	04035324018437	2010-01-01
312-10-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff and double fenestration at inner and outer bend	04035324018444	2010-01-01
313-07	Tracoe Twist Plus tracheostomy tube	04035324018109	2010-01-01
313-08	Tracoe Twist Plus tracheostomy tube	04035324018123	2010-01-01
313-09	Tracoe Twist Plus tracheostomy tube	04035324019130	2010-01-01
313-10	Tracoe Twist Plus tracheostomy tube	04035324018147	2010-01-01
314-07	Tracoe Twist Plus tracheostomy tube with double fenestration at inner and outer bend	04035324018154	2010-01-01

314-08	Tracoe Twist Plus tracheostomy tube with double fenestration at inner and outer bend	04035324018161	2010-01-01
314-09	Tracoe Twist Plus tracheostomy tube with double fenestration at inner and outer bend	04035324018178	2010-01-01
314-10	Tracoe Twist Plus tracheostomy tube with double fenestration at inner and outer bend	04035324018185	2010-01-01
316-07	Tracoe Twist Plus tracheostomy tube with low pressure cuff and subglottic suction line	04035324019076	2011-12-01
316-08	Tracoe Twist Plus tracheostomy tube with low pressure cuff and subglottic suction line	04035324019083	2011-12-01
316-09	Tracoe Twist Plus tracheostomy tube with low pressure cuff and subglottic suction line	04035324019090	2011-12-01
316-10	Tracoe Twist Plus tracheostomy tube with low pressure cuff and subglottic suction line	04035324019106	2011-12-01
316-07-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff and subglottic suction line	04035324019205	2011-12-01
316-08-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff and subglottic suction line	04035324019229	2011-12-01
316-09-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff and subglottic suction line	04035324019236	2011-12-01
316-10-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff and subglottic suction line	04035324019243	2011-12-01
888-316-07	Tracoe Twist Plus tracheostomy tube with low pressure cuff, subglottic suction line and double fenestration at inner and outer bend	04035324018895	2011-12-01
888-316-08	Tracoe Twist Plus tracheostomy tube with low pressure cuff, subglottic suction line and double fenestration at inner and outer bend	04035324018901	2011-12-01
888-316-09	Tracoe Twist Plus tracheostomy tube with low pressure cuff, subglottic suction line and double fenestration at inner and outer bend	04035324018925	2011-12-01
888-316-10	Tracoe Twist Plus tracheostomy tube with low pressure cuff, subglottic suction line and double fenestration at inner and outer bend	04035324018932	2011-12-01
888-316-07-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff, subglottic suction line and double fenestration at inner and outer bend	04035324019168	2011-12-01
888-316-08-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff, subglottic suction line and double fenestration at inner and outer bend	04035324019175	2011-12-01
888-316-09-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff, subglottic suction line and double fenestration at inner and outer bend	04035324019182	2011-12-01
888-316-10-P	Tracoe Twist Plus tracheostomy tube with minimally traumatic inserter, low pressure cuff, subglottic suction line and double fenestration at inner and outer bend	04035324019199	2011-12-01

521-07	Tracoe Twist Plus spare inner cannulas with 15mm connector	04035324018192	2010-01-01
521-08	Tracoe Twist Plus spare inner cannulas with 15mm connector	04035324018208	2010-01-01
521-09	Tracoe Twist Plus spare inner cannulas with 15mm connector	04035324018215	2010-01-01
521-10	Tracoe Twist Plus spare inner cannulas with 15mm connector	04035324018222	2010-01-01
521-07-X	Tracoe Twist Plus spare inner cannulas with 15mm connector	04035324018239	2010-01-01
521-08-X	Tracoe Twist Plus spare inner cannulas with 15mm connector	04035324018246	2010-01-01
521-09-X	Tracoe Twist Plus spare inner cannulas with 15mm connector	04035324018253	2010-01-01
521-10-X	Tracoe Twist Plus spare inner cannulas with 15mm connector	04035324018260	2010-01-01
521-08-XXX	Tracoe Twist Plus spare inner cannulas with 15mm connector	04035324027996	2016-05-01
521-09-XXX	Tracoe Twist Plus spare inner cannulas with 15mm connector	04035324028009	2016-05-01
523-07	Tracoe Twist Plus spare inner cannulas double fenestrated, with 15mm connector	04035324018277	2010-01-01
523-08	Tracoe Twist Plus spare inner cannulas double fenestrated, with 15mm connector	04035324018284	2010-01-01
523-09	Tracoe Twist Plus spare inner cannulas double fenestrated, with 15mm connector	04035324018291	2010-01-01
523-10	Tracoe Twist Plus spare inner cannulas double fenestrated, with 15mm connector	04035324018307	2010-01-01
523-07-X	Tracoe Twist Plus spare inner cannulas double fenestrated, with 15mm connector	04035324018321	2010-01-01
523-08-X	Tracoe Twist Plus spare inner cannulas double fenestrated, with 15mm connector	04035324018338	2010-01-01
523-09-X	Tracoe Twist Plus spare inner cannulas double fenestrated, with 15mm connector	04035324018345	2010-01-01
523-10-X	Tracoe Twist Plus spare inner cannulas double fenestrated, with 15mm connector	04035324018352	2010-01-01
330-07	Tracoe Experc set Twist Plus including REF 311-P with cuff and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324018741	2010-01-01
330-08	Tracoe Experc set Twist Plus including REF 311-P with cuff and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324018758	2010-01-01
330-09	Tracoe Experc set Twist Plus including REF 311-P with cuff and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324018765	2010-01-01
330-10	Tracoe Experc set Twist Plus including REF 311-P with cuff and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324018772	2010-01-01

331-07	Tracoe Experc set Twist Plus including REF 312-P with cuff, double fenestrated and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324018789	2010-01-01
331-08	Tracoe Experc set Twist Plus including REF 312-P with cuff, double fenestrated and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324018796	2010-01-01
331-09	Tracoe Experc set Twist Plus including REF 312-P with cuff, double fenestrated and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324018802	2010-01-01
331-10	Tracoe Experc set Twist Plus including REF 312-P with cuff, double fenestrated and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324018826	2010-01-01
332-07	Tracoe Experc set Twist Plus including REF 316-P with cuff, subglottic suction line and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324019250	2012-01-01
332-08	Tracoe Experc set Twist Plus including REF 316-P with cuff, subglottic suction line and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324019267	2012-01-01
332-09	Tracoe Experc set Twist Plus including REF 316-P with cuff, subglottic suction line and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324019274	2012-01-01
332-10	Tracoe Experc set Twist Plus including REF 316-P with cuff, subglottic suction line and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324019281	2012-01-01
888-332-07	Tracoe Experc set Twist Plus including REF 888-316-P with cuff, double fenestrated, subglottic suction line and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324019441	2012-04-01
888-332-08	Tracoe Experc Set Twist Plus including REF 888-316-P with cuff, double fenestrated, subglottic suction line and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324019458	2012-04-01
888-332-09	Tracoe Experc set Twist Plus including REF 888-316-P with cuff, double fenestrated, subglottic suction line and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324019465	2012-04-01
888-332-10	Tracoe Experc set Twist Plus including REF 888-316-P with cuff, double fenestrated, subglottic suction line and minimally traumatic insertion system (and Tracoe Experc Dilation Set REF 520)	04035324019472	2012-04-01