

<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>	The compresses are designed to protect the skin environment of a tracheostoma of neonates, children, adolescents and adults (for respective patient population of the single references see device description). Their main functions are: <ul style="list-style-type: none"> <li>• Absorbing secretions from the tracheostoma</li> <li>• Provide padding between the tracheostoma and the neck plate of the tracheostomy tube</li> <li>• Protecting the skin beneath the neck flange</li> <li>• Protecting the tracheostoma from foreign bodies (ref 908 and 909)</li> </ul> The compresses are intended for single use only.
<b>Basic UDI-DI</b>	4035324COMPR_UNSTERILEZS
<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:

<b>Catalogue Number</b>	<b>Product Name</b>	<b>UDI-DI</b>	<b>Original CE Marking Date yyyy-mm-dd</b>
REF 905	Tracoe Compress AL	04035324047413	2003-03-01
REF 907-A	Tracoe Compress Two-ply	04035324063819	2003-03-01
REF 907-B	Tracoe Compress Two-ply,slit	04035324011568	2003-03-01
REF 908	Tracheostoma Protection, small, with adhesive strip suitable for children, teenagers and adults	04035324047710	2003-03-01
REF 909	Tracheostoma Protection, large, with adhesive strip suitable for children, teenagers and adults	04035324047819	2003-03-01
REF 910-A	Tracoe Compress	04035324061211	2003-03-01
REF 910-B	Tracoe Compress, Slit	04035324061310	2003-03-01
REF 957	Tracoe Compress Coated Two-ply, Slit	04035324011605	2003-03-01
REF 960	Tracoe compress coated, Slit	04035324011629	2003-03-01
REF 961	Tracoe Compress Slit Kids	04035324012572	2003-03-01
REF 969	Tracoe Softpad	04035324015085	2003-03-01