

Certificate

The Certification Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith confirms that the company

**Transcoject GmbH
Rügenstr. 8
24539 Neumünster
Germany**

has introduced, applies and maintains a Quality Management System in the area of:

**Design, manufacture, packaging, sterilization, final inspection and
distribution of medical products according to attachment 1**

The compliance of the Quality Management System with the requirements of the below mentioned standard was verified by an audit:

EN ISO 13485:2016

The license of certification is subject to surveillance by MEDCERT.

This certificate is valid until: 07 November 2021

Report No.: 0520FS26F
Process No.: QS – 0520
Certificate No.: 0520GB445190716

Hamburg, 16 July 2019



MEDCERT Certification Body
(Dr. Andreas Schich)

**Attachment 1
Certificate QS – 0520**

This attachment is valid only in connection with certificate No.: 0520GB445190716

Design, manufacture, sterilization and final inspection of

- syringes for single use
- application-devices
- connectors
- syringe ampoules and closure devices

Packaging and sterilization of

- cannulas

Design, manufacture and final inspection of

- sterile prefilled application-systems

Distribution of

- dressing materials

Hamburg, 16 July 2019



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Deutsche
Akkreditierungsstelle
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