

Certificate

The Certification Body

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

herewith certifies that the company

Transcoject GmbH Rügenstr. 8 24539 Neumünster Germany

has introduced, applies and maintains a quality management system in the area of activities, products/services and locations listed in the appendix.

The conformity of this quality management system to the requirements of the following standard has been verified by an audit:

EN ISO 13485:2016

This certification is subject to surveillance by MEDCERT.

Effective date: Expiry date:

2021-12-27 2024-11-06

Report No.:

0520FS29F QS – 0520

Procedure No.: Certificate No.:

0520GB445211227B

Hamburg, 2021-12-27

MEDCERT Certification Body Marcus Harder

The certificate is only valid when provided entirely with all of its pages. To verify the validity of this certificate, contact info@medcert.de.

MEDCERT is a management systems certification body accredited by DAkkS.





Appendix of certificate

Procedure No.:

QS - 0520

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Activities and products/services in the scope of certification

Sterilization of disposable medical devices with Ethylenoxide abiding by the EN ISO 11135:2014/A1:2019 standard

Locations in the scope of certification

Transcoject GmbH Rügenstr. 8 24539 Neumünster Germany

This appendix is integral part of the above-referenced certificate.

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