





Certificate

No. Q5 001450 0020 Rev. 02

Holder of Certificate: Corcym Canada Corp.

> 5005 North Fraser Way Burnaby BC V5J 5M1

CANADA

Corcym Canada Corp. Facility(ies):

5005 North Fraser Way, Burnaby BC V5J 5M1, CANADA

See Scope of Certificate

Certification Mark:



Scope of Certificate: Design and Development, Production and

Distribution of:

- Biological Heart Valve Prostheses and

Accessories

- Accessories for Mechanical Heart Valve

Prostheses and Repair Products

EN ISO 13485:2016 **Applied Standard(s):**

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 001450 0020 Rev. 02

Report No.: 7169011363

Valid from: 2022-08-30 Valid until: 2024-02-28

Christoph Dicks Date, 2022-08-30

Head of Certification/Notified Body







Product Service

Certificate

No. Q5 001664 0019 Rev. 02

Holder of Certificate: Corcym S.r.l.

Via Crescentino sn 13040 Saluggia (VC)

ITALY

Certification Mark:



Scope of Certificate:

Design and development, manufacture and distribution of medical devices intended for cardiac surgery and interventional cardiology, including implantable medical devices and their components, such as mechanical and biological heart valves, annuloplasty rings, aortovalvular prostheses, valved conduits and related

accessories.

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 001664 0019 Rev. 02

Report No.: ITA1663134

 Valid from:
 2021-05-25

 Valid until:
 2024-03-31

Date, 2021-05-10 Christoph Dicks

Head of Certification/Notified Body

TÜV®



Certificate

No. Q5 001664 0019 Rev. 02

Applied Standard(s): EN ISO 13485:2016

Medical devices - Quality management systems -

Requirements for regulatory purposes

(ISO 13485:2016) DIN EN ISO 13485:2016

Facility(ies): Corcym S.r.l.

Via Crescentino sn, 13040 Saluggia (VC), ITALY

Design and development, manufacture and distribution of medical devices intended for cardiac surgery and interventional cardiology, including implantable medical devices and their components, such as mechanical and biological heart valves, annuloplasty rings, aortovalvular prostheses, valved conduits and related accessories.

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