



Certificate

No. Q5 077874 0007 Rev. 02

Holder of Certificate: **Technowood Corporation**
Kohoku Factory
4-30-19 Kohoku, Adachi-Ku
Tokyo
123-0872 JAPAN

Certification Mark:



Scope of Certificate: **Design and Development, Production, Distribution, Installation and Servicing of Heart-lung machines. Design and Development, Production, Distribution of Extracorporeal circuit systems for artificial heart-lungs, Angiographic catheters, Catheter guide wires. Production and Distribution of Endomyocardial biopsy forceps. Production (labeling only) and Distribution of Extracorporeal circuit systems for artificial heart-lungs, Blood filters, Hemoconcentrators for extracorporeal circuit systems or artificial heart-lungs, Angiographic catheters, Catheter guide wires and Endomyocardial biopsy forceps.**

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 077874 0007 Rev. 02

Report No.: **JA1744325**

Valid from: **2022-04-01**

Valid until: **2025-03-31**

Date, **2022-02-03**



Christoph Dicks

Head of Certification/Notified Body

Certificate

No. Q5 077874 0007 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): **Technowood Corporation Kohoku Factory**
4-30-19 Kohoku, Adachi-Ku, Tokyo, 123-0872 JAPAN

Design and Development, Production, Distribution,
Installation and Servicing of Heart-lung machines.
Design and Development, Production, and Distribution of
Extracorporeal circuit systems for artificial heart-lungs,
Angiographic catheters, Catheter guide wires.
Production and Distribution of Endomyocardial biopsy forceps.

Technowood Corporation Soka Office
3-24-1 Inari, Soka City, Saitama Prefecture, 340-0003 JAPAN

Production (labeling only) and Distribution of Extracorporeal circuit
systems for artificial heart-lungs, Blood filters, Hemoconcentrators
for extracorporeal circuit systems or artificial heart-lungs,
Angiographic catheters, Catheter guide wires and Endomyocardial
biopsy forceps.

-/-