CERTIFICATE

Number: 2223522

The management system of:

Bioptimal International PTE. LTD.

36 Jalan Tukang 619266 Singapore Singapore

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

Design, manufacture and distribution of Thermodilution, Pulmonary Artery, Central Venous, Embolectomy devices and Bipolar Pacing Catheters, Pressure Monitoring Systems. Assembly and distribution of Angiographic Kits and Surgical Procedure Set for Catheter Introduction. Including purchase and resale of accessories for critical care products

Certificate expiry date: 14 January 2025
Certificate effective date: 14 January 2022
Certified since: 28 January 2019

DEKRA Certification B.V.

B.T.M. Holtus Managing Director

J.A. van Vugt Certification Manager

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