

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.: 10000377188-PA-NA-SVK Initial certification date: 30 November 2021 Valid: 30 November 2021 – 30 November 2024

This is to certify that the management system of **SMART Clinical Products B.V.** Ekkersrijt 4301, 5692 DJ Son en Breugel, Netherlands

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

DESIGN, MANUFACTURING, SALES AND DISTRIBUTION OF STERILE AND NON-STERILE DISPOSABLE MEDICAL DEVICES ID-SYSTEM FOR OPEN CARDIO SURGERY AND DISTRIBUTION OF STERILE AND NON STERILE, AS WELL AS ACTIVE AND NON ACTIVE CARDIO SURGERY AND CARDIO THERAPY MEDICAL DEVICES DESIGNED FOR CARDIO SURGERY AND CARDIO THERAPY.

Place and date: Høvik, 30 November 2021



For the issuing office: DNV Product Assurance AS Veritasveien 3, 1363 Høvik, Norway

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Cecilie Gudesen Torp Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. ACCREDITED UNIT: DNV Business Assurance Norway AS, Veritasveien 1, 1363 Høvik, Norway - TEL: +47 67 57 99 00. www.dnv.no/assurance