

CERTIFICATE

Number: 6051352

The management system of the organization(s) and locations mentioned on the addendum belonging to:

Apex Medical Co., Ltd.

Building 5, No.1019 Liaohe Road, Xinbei District
213000 Changzhou, Jiangsu
China

including the implementation meets the requirements of the standard:

EN ISO 13485:2016

Scope:

Design, Development, Manufacture and Distribution of Insulin Pumps, Infusion Pumps, Sterilized Infusion Sets for Single Use, Sterile ambulant drug reservoirs, Large Volume Infusion Apparatus, Sterile Disposable Infusion Kits including Medication Cassette Reservoir, Extension Set, Administration Set for the area of intravenous, subcutaneous or peripheral nerve block infusion

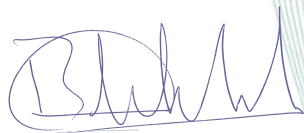
Certificate expiry date: 1 December 2028

Certificate effective date: 1 December 2025

Certified since: 9 December 2019

This certificate is valid for the organization(s) and/or locations mentioned on the addendum.

DEKRA Certification B.V.



B.T.M. Holtus
Managing Director



J.M. McKenzie
Certification Manager

© Integral publication of this certificate and adjoining reports is allowed



ADDENDUM

To certificate: 6051352

The management system of the organization(s) and/or location(s) of:

Apex Medical Co., Ltd.

Building 5, No.1019 Liaohe Road, Xinbei District
213000 Changzhou, Jiangsu
China

Certified organization(s) and/or locations:

Different scope

Apex Medical Co., Ltd.
209 Bld., No.35 South Changjiang
Road, Xinwu District
214028 Wuxi, Jiangsu
China

Manufacture and Distribution of Insulin Pumps, Infusion Pumps,
Sterilized Infusion Sets for Single Use, Sterile ambulant drug
reservoirs for the area of intravenous, subcutaneous or
peripheral nerve block infusion

Addendum expiry date: 1 December 2028
Addendum effective date: 1 December 2025