EC Certificate Full Quality Assurance System: Certificate KR19/81826293.00

The management system of

Ace Medical Co., Ltd. also trading as Ace Medical Co., Ltd. Okcheon Factory

(HO&Factory) 33, Naeyoo-Road124, Deogyang-Gu
Goyang-Si, Gyeonggi-Do, Korea

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

The scope of registration appears on page 2 of this certificate.

This certificate is valid from 16 December 2019 until 05 February 2024
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 05 February 2001
and first certified by SGS Belgium NV since 16 December 2019

Multiple certificates have been issued for this scope.
The main certificate is numbered KR19/81826293.00

This is a multi-site certification.
Additional site details are listed on subsequent pages

Certification is based on reports numbered WW/PCI 201592

Authorised by

SGS Belgium NV, Notified Body 1639
SGS House Noorderlaan 87 2030 Antwerp Belgium
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Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

Issue 1

Detailed scope

PCA infusion pumps (Model : AutoMed® 3300, AutoMed® 3400) ;
Sterile single-use PCA infusion pumps (Model : AutoMed® 3200) ;
Sterile single-use elastomeric infusion pumps (Model : AutoFuser, AutoFuser S)
Sterile single-use elastomeric infusion pumps with flow regulator (Model : AutoSelector, AutoSelector S) ;
Sterile single-use In-line closed suction system (Model : AceTrachcare) ;
Sterile single-use reservoir bags and tubing sets(Model : AutoMed Set);
Sterile single-use invasive blood pressure monitoring system (Model : AutoTransducer) ;
Thermal warmers for blood/fluid infusion (Model : AutoMer, AutoMer2) ;
Sterile single-use blood/fluid transfer sets for thermal warmers (Model : AutoMer Set, AutoMer Set II) ;
Automatic pressure infuser for blood/fluid bags (Model : AutoPC, AutoPC2, AutoPC2 rechargeable type) ;
Sterile single-use catheter set(Model : Ace Catheter Set);
Sterile single-use catheter with elastomeric infusion pump (Model : AutoFuser catheter kit and AutoSelector catheter kit) ;
Sterile single-use epidural set (Model : Epina, Epina Plus and Epipla) ;
Sterile single-use thoracotomy tunneler;
Heated humidifier (Model : Heated Controller) ;
PCA Ambulatory infusion pump (Model : AutoClamp) and Sterile single use IV set (Model : AutoClamp Filter Set);
Sterile single-use heated humidification circuit system for anesthesia (Model : Mega Acer Kit)

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

(Factory2) 47, Uiryodanji-Gil, Okcheon-Eup, Okcheon-Gun, Chungcheongbuk-Do, Korea

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