EC Certificate Full Quality Assurance System: Certificate TW14/10344.03

The management system of

Rossmax Swiss GmbH

Tramstrasse 16, CH-9442, Berneck, Switzerland

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

1. Clinical digital thermometer
2. Infrared ear/temple thermometer
3. Nebulizer (including nebulizer pack and nebulizer bottle set) for respiratory therapy
4. Non-invasive blood pressure measuring device and aneroid sphygmomanometer
5. Non invasive blood pressure measuring device with pulse arrhythmia detecting function (includes AFib (Atrial Fibrillation), PC (Premature Contraction), TACH (Tachycardia) and BRAD (Bradycardia))
6. Powered suction unit.

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.

This certificate is valid from 22 May 2017 until 22 May 2022 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 18 March 2020
Issue 7. Certified since 28 March 2012

Certification is based on reports numbered TW/TPE VW604603

Multiple certificates have been issued for this scope
The main certificate is numbered TW14/10344.00

Authorised by

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