EC Certificate Full Quality Assurance System: Certificate TW19/20056

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

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 20 February 2020 until 22 May 2022
and remains valid subject to satisfactory surveillance audits.
Issue 1. Certified since 28 March 2012
and first certified by SGS Belgium NV since 20 February 2020

Certification is based on reports numbered TW/TPE VW604603

Authorised by

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