EC Certificate Full Quality Assurance System: Certificate TW19/20056

The management system of

Rossmax Swiss GmbH

Widnauerstrasse 1, CH-9435 Heerbrugg, 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, 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 27 April 2021 until 22 May 2023
and remains valid subject to satisfactory surveillance audits.
Issue 3. Certified since 28 March 2012

Certification is based on reports numbered TW/TPE VW604603

Authorised by

Global Medical Devices Head of Notified Body

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