



Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 16 04 66754 007

Manufacturer: Cardia Innovation AB

Månskärsvägen 10 B
141 75 Kungens Kurva
SWEDEN



Facility(ies):

Cardia Innovation AB
Månskärsvägen 10 B, 141 75 Kungens Kurva, SWEDEN

Product

Category(ies):

Gas diffusers / gas diffusers for open surgery

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713082121

Valid from: 2016-06-01

Valid until: 2018-07-09



Date, 2016-06-01

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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