Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH · 90431 Nürnberg

Ms. Tina Juneau
Datex-Ohmeda, Inc.
3030 Ohmeda Drive
PO Box 7550
MADISON WI 53707-7550
USA

Contact

Tel. +49 911 655-5225
Mail service@de.tuv.com

Date November 11, 2019

Application for : Vollst. QMS, Anhang II MDD
Certificate No. : HD 60144148 Sheet 0001
Device : Only for QM-System audit
Test requirement : Richtlinie 93/42/EWG

Dear Ms. Juneau,

Enclosed please find the new certificate No. HD 60144148 0001 replacing the previous certificate.

With effective date of the new certificate, the previous certificate (number see new certificate) becomes invalid.

Kind regards

Certification body

S. Liu Songli

Test sample: no, documentation available

TÜV Rheinland
LGA Products GmbH

Tillystraße 2
90431 Nürnberg

Tel. +49 911 655-5225
Fax +49 911 655-5226
Mail service@de.tuv.com
Web www.tuv.com/safety

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60144148 0001

Report No.: 31793762 001

Manufacturer:
Datex-Ohmeda, Inc.
3030 Ohmeda Drive
PO Box 7550
MADISON WI 53707-7550
USA

Products:
Anesthesia and Vaporizer Systems,
Ventilators and Patient Circuits (single use)

Replaces Approval, Registration No.: 60109676 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-11-11

Date: 2019-11-11

Notified Body

S. Liu

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.