ZERTIFIKAT ◆ CERTIFICATE ◆ 認証証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Product Service

CERTIFICATE

No. Q1N 16 12 20809 040

Holder of Certificate: **BREAS Medical AB**
Företagsvägen 1
SE-435 33 Mölnlycke
SWEDEN

Facility(ies):
BREAS Medical AB
Företagsvägen 1, SE-435 33 Mölnlycke,
SWEDEN

Human Design Medical LLC
57 Chapel Street, Suite 200, Newton, MA 02458,
USA

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production, Distribution, Service and Marketing of Respiratory Therapy Systems, Respiratory Monitoring Systems, Sleep Apnea- and Humidifier Systems**

Applied Standard(s):
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713091720

Valid from: 2017-01-25
Valid until: 2019-03-31

Date, 2017-01-25

Stefan Preiß

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