



Product Service

CERTIFICATE

No. Q1N 16 01 20809 036

Holder of Certificate: BREAS Medical AB

Företagsvägen 1
43533 Mölnlycke
SWEDEN

Facility(ies):

BREAS Medical AB
Företagsvägen 1, 43533 Mölnlycke, SWEDEN

Human Design Medical LLC
119 Braintree Street, Suite 703, Boston, MA
02134, USA



Certification Mark:



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):

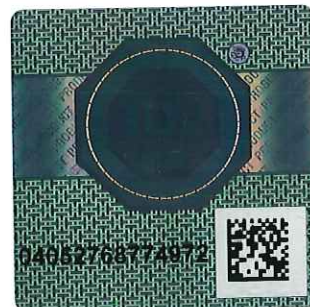
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012

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.: 713074224

Valid from: 2016-04-01

Valid until: 2019-03-31



S. Preiß

Date, 2016-03-09

Stefan Preiß

Page 1 of 1

