Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EG Bescheinigung

Vollständiges Qualitätssicherungssystem
Richtlinie 93/42/EWG über Medizinprodukte (MDD), Anhang II ohne (4)
(Produkte in Klasse IIa, IIb oder III)

Nr. G1 089195 0005 Rev. 00

Hersteller:

IQE GmbH
Gewerbestr. 8
16540 Hohen Neuendorf
DEUTSCHLAND

Produktkategorie(n):

Medizinprodukte für Hypo- /Hyper Oxy-Therapie

Die Zertifizierstelle der TÜV SÜD Product Service GmbH bescheinigt hiermit, dass der genannte Hersteller ein Qualitätssicherungssystem für die Auslegung, die Fertigung und die Endkontrolle der betreffenden Produkte / Produktkategorien entsprechend MDD Anhang II anwendet. Dieses Qualitätssicherungssystem erfüllt die Anforderungen dieser Richtlinie und unterliegt der regelmäßigen Überwachung. Zum Inverkehrbringen von Klasse III Produkten ist zusätzlich eine Bescheinigung nach Anhang II (4) erforderlich. Umseitige Hinweise sind zu beachten.

Bericht Nr.: 713168878

Gültig ab: 2020-05-04
Gültig bis: 2024-05-26

Datum, 2020-05-04

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH ist Benannte Stelle mit der Kennnummer 0123

TÜV SÜD Product Service GmbH • Zertifizierstelle • Ridlerstraße 65 • 80339 München • Deutschland

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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ZLG-BS-244.10.08

TÜV SÜD 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 089195 0005 Rev. 00

Manufacturer: **IQE GmbH**
Gewerbestr. 8
16540 Hohen Neuendorf
GERMANY

Product Category(ies): **Medical devices for Hypo- /Hyper Oxy-Therapy**

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.: 713168878

Valid from: 2020-05-04
Valid until: 2024-05-26

Date, 2020-05-04

Christoph Dicks
Head of Certification/Notified Body

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

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DECLARATION OF CONFORMITY

Manufacturer	*IQE GmbH*
Manufacturer Address	*Gewerbestr. 8* *16540 Hohen Neuendorf/Germany*
Medical Device	CellAirOne
Product identification	48 1100
Classification	*Class IIa* (according to Annex IX to Council Directive 93/42/EEC, rule 11)

The manufacturer declares under the sole responsibility that the medical device(s) described above conform to the applicable provisions of the Council Directives

- 93/42/EEC (Medical Devices)

- 2011/65 (RoHS)

and their amendments as transposed in the national laws of the Member States.

Any modification of the medical device not authorized by IQE GmbH will nullify this declaration.

The identification number of the Notified Body form implementation of the procedure set in Annex II without (4) to the above Directive is 0123 (only valid for 93/42EEC):

Certificate No.: G1 089195 0005 Rev. 00

TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München

Valid from (lowest serial number): 483400

Valid until: 2024-05-26

The validity of this Declaration of conformity could be reduced if the validity of the Certificate mentioned above would be reduced. The validity of the actual EC-Certificate can be checked via the homepage of TÜV Süd.

This declaration is based on the technical documents which demonstrate that the product complies with the requirements of the Directives mentioned above.

Place and date: *Hohen Neuendorf, 05.05.2020*

Signature:

Name: Johannes Dietrich (CEO)

EC Declaration of Conformity

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 089195 0006 Rev. 00

Holder of Certificate: **IQE GmbH**
Gewerbestr. 8
16540 Hohen Neuendorf
GERMANY

Facility(ies):
IQE GmbH
Gewerbestr. 8, 16540 Hohen Neuendorf, GERMANY

Design and Development, Production, Sales and Service of Medical devices for Hypo- / Hyper Oxy-Therapy, Physiotherapy and Rehabilitation

Certification Mark:

Scope of Certificate: **Design and Development, Production, Sales and Service of medical devices for Hypo- / Hyper Oxy-Therapy, Physiotherapy and Rehabilitation**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

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). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 089195 0006 Rev. 00

Report No.: 713191137

Valid from: 2021-01-08
Valid until: 2023-11-27

Date, 2021-01-08

Christoph Dicks
Head of Certification/Notified Body

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