

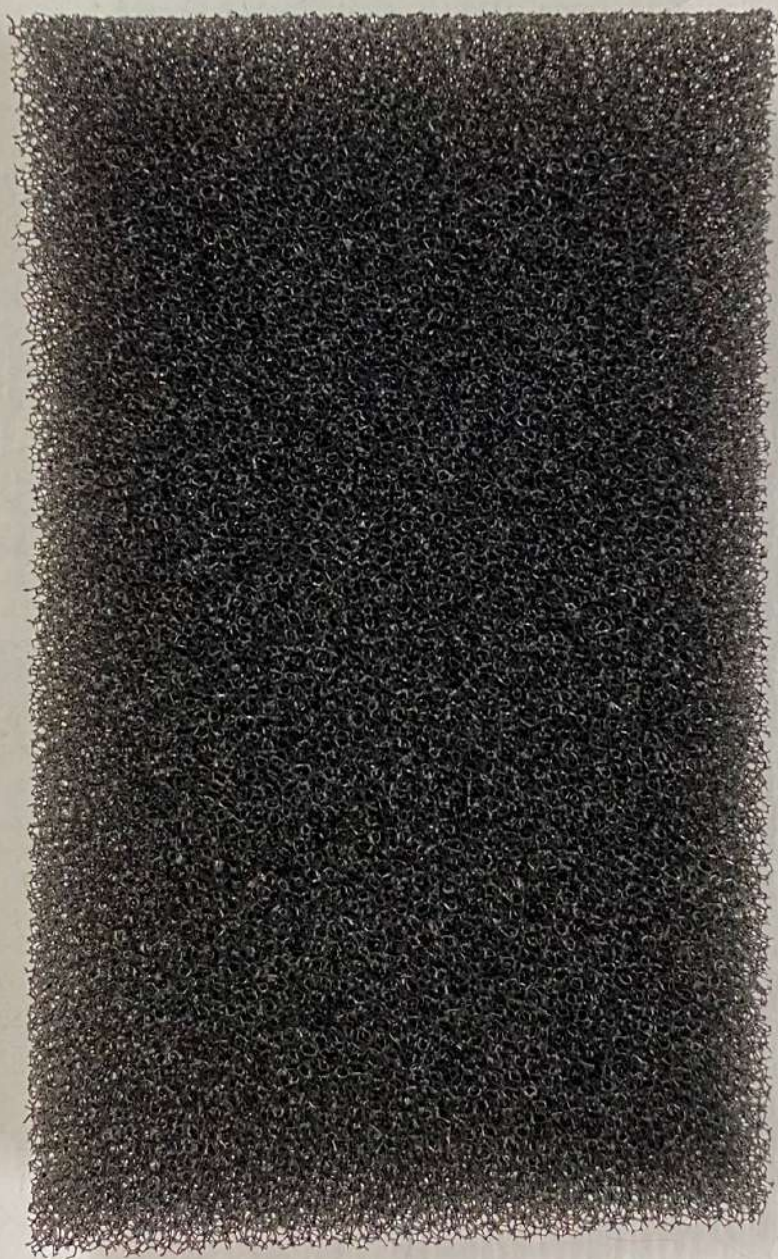


QTY: 2
N.W.: 9
G.W.: 11.0
Size: 54.0x36.0

RespiroX
PORTABLE

QTY: 2
N.W.: 9

830
444 (8)











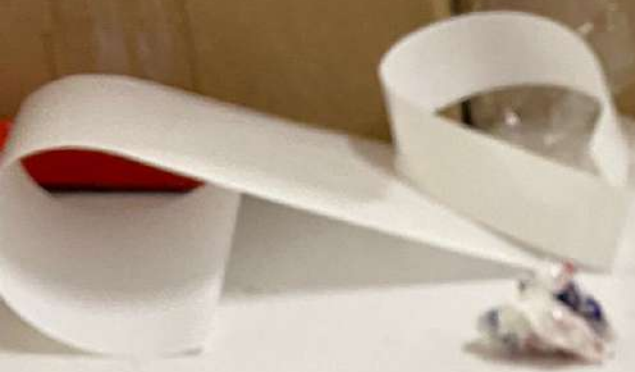






RespiroX
RespiroX
RespiroX







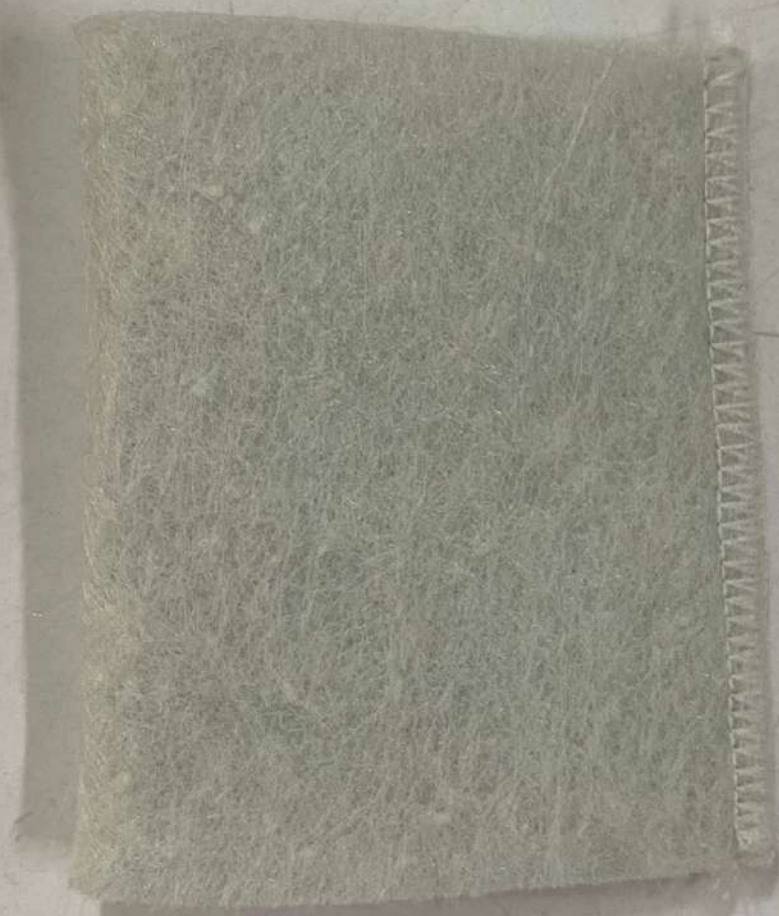
RespiroX





RespiroX
RespiroX
RespiroX









Product Service

EC Certificate

Production Quality Assurance System

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

No. G2 18 01 96468 004

Manufacturer: **Jiangsu Shuangsheng
Medical Appliance Co., Ltd.**

Dandong Industrial Park, Danyang City
(No.12 Lingkou 122 Highway Industrial Zone)
212353 Danyang
PEOPLE'S REPUBLIC OF CHINA



EC-Representative: **Prolinx GmbH**

Brehmstr. 56
40239 Duesseldorf
GERMANY

**Product
Category(ies):** **Oxygen Concentrator,
Portable Phlegm Suction Unit,
Nebulizer**

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

Report No.: SH18109202

Valid from: 2018-05-29

Valid until: 2022-06-27



Date, 2018-05-29

Stefan Preiß

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

Page 1 of 2



Product Service

EC Certificate

Production Quality Assurance System

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

No. G2 18 01 96468 004

Facility(ies):

Jiangsu Shuangsheng Medical Appliance Co., Ltd.
Dandong Industrial Park, Danyang City, (No.12 Lingkou
122 Highway Industrial Zone), 212353 Danyang,
PEOPLE'S REPUBLIC OF CHINA

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ CERTIFICADO ◆ CERTIFICAT



Certificate

No. Q6 096468 0007 Rev. 00

Holder of Certificate: **Jiangsu Shuangsheng
Medical Appliance Co., Ltd.**
Dandong Industrial Park, Danyang City
(No.12 Lingkou 122 Highway Industrial Zone)
212353 Danyang
PEOPLE'S REPUBLIC OF CHINA

Facility(ies): Jiangsu Shuangsheng Medical Appliance Co., Ltd.
Dandong Industrial Park, Danyang City, (No.12 Lingkou 122
Highway Industrial Zone), 212353 Danyang, PEOPLE'S
REPUBLIC OF CHINA

Certification Mark:



Scope of Certificate: **Production and Distribution of
Oxygen Concentrator,
Portable Phlegm Suction Unit,
Nebulizer, Anti Decubitus Mattress**

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 (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH20109204

Valid from: 2020-07-06

Valid until: 2023-06-27

Date, 2020-07-06

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD TÜV SÜD
ZERTIFIKAT ◆ CERTIFICATE ◆ 認證書 ◆ CERTIFICADO ◆ CERTIFICAT