KINGLINE
GMBH

HYDROX
STERILWASSER

Zertifiziert und Evaluiert

Zur Inhalation geeignet

Persönliche Experten-Beratung

Version: 1.1 | Freigabe: 29.11.2022

sales@kingline.de | +49 (0) 9135 - 5718390

Kingline GmbH | Am Altenbach 7 | 91341 Röttenbach

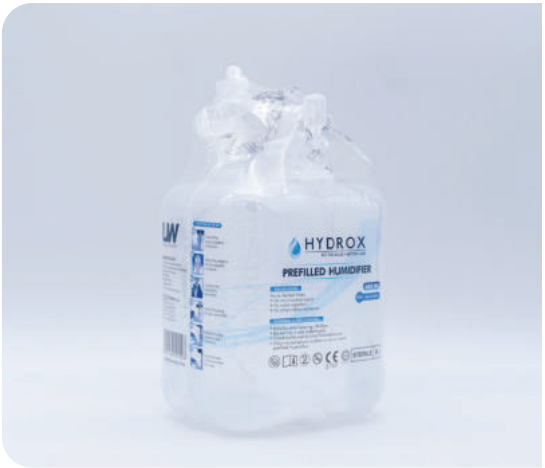
PERSÖNLICHE EXPERTEN-BERATUNG

LEICHT ZU HANDHABEN

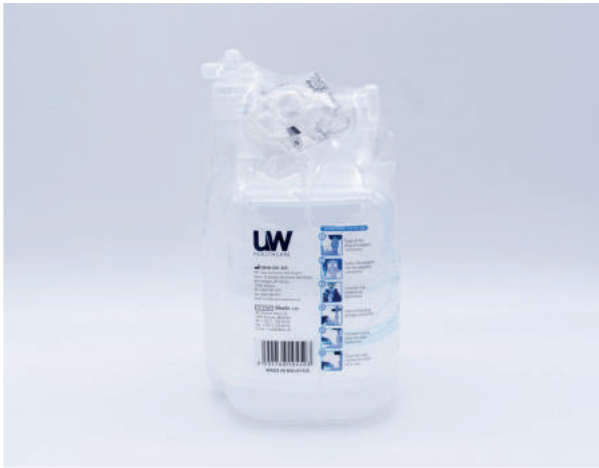
ZUR INHALATION GEEIGNET

CE-ZERTIFIZIERT (CE-2797)

PRODUKTBILDER



Vorderansicht



Rückseite

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DETAILINFORMATIONEN

CE-Kennzeichnung	CE 2797
Verwendungszweck	für Atemgase und Befeuchter mit Makroverneblung zur Inhalation
Nutzungsbeschränkung	nicht zur Injektion geeignet
Haltbarkeit (ab Produktionsdatum)	5 Jahre
Verfügbare Sprachen des Handbuchs	Englisch
Gewindegröße	9/16“ - 18 (auch bekannt als DISS)

LOGISTIKDATEN

VPE	25 Stk. / 450 ml
VPE Gewicht	14,5 kg
VPE Maße	50x50x19 cm
VPE pro EPAL	44 VPE (1.100 Stk.)
EPAL pro LKW	22 EPAL (19.800 Stk.)
EPAL Gewicht	645 kg
EPAL Maße (B x H x T)	106x106x233 cm
Lagertemperatur	min. 5 °C; max. 60°C

DISTRITBUTION

Hersteller	UWHM Sdn. Bhd. PMT 790, Jalan Cassia Selatan 5/2, Taman Perindustrian Batu Kawan, Bandar Cassia, Pulau Pinang 14110 Malaysia
EC-REP	Obelis s.a. Bd. Général Wahis 53 1030 Brussels, BELGIUM

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By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 618037**

Issued To: **UWHM Sdn. Bhd.**
987,
Jalan Perindustrian Bukit Minyak 7, Mukim 13
Kawasan Perindustrian Bukit Minyak
Bukit Mertajam, SPT Penang
14000
Malaysia

In respect of:

Manufacture of sterile prefilled humidifiers for respiratory gases

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack, Senior Vice President Medical Devices

First Issued: **2015-07-28** Date: **2020-03-19** Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Supplementary Information to CE 618037

Issued To:

UWHM Sdn. Bhd.
987,
Jalan Perindustrian Bukit Minyak 7, Mukim 13
Kawasan Perindustrian Bukit Minyak
Bukit Mertajam, SPT Penang
14000
Malaysia

Number	Device name	Intended purpose
Class IIa		
MD 0101	Sterile Prefilled Humidifier	N/A

First Issued: **2015-07-28** Date: **2020-03-19** Expiry Date: **2024-05-26**

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EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

Certificate No:	**CE 618037**
Date:	**2020-03-19**
Issued To:	**UWHM Sdn. Bhd.** **987,** **Jalan Perindustrian Bukit Minyak 7, Mukim 13** **Kawasan Perindustrian Bukit Minyak** **Bukit Mertajam, SPT Penang** **14000** **Malaysia**

Subcontractor:	**Service(s) supplied**
Obelis s.a Bd. Général Wahis 53 1030 Brussels Belgium	**EU Representative**
Synergy Sterilisation (M) Sdn Bhd. Plot 203 Kuala Ketil Industrial Estate Kuala Ketil Kedah 09300 Malaysia	**Radiation (Gamma Sterilization)**
UWHM Sdn. Bhd. PMT 790, Jalan Cassia Selatan 5/2 Taman Perindustrian Batu Kawan Bandar Cassia Pulau Pinang 14110 Malaysia	**Manufacture**

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EC Certificate - Production Quality Assurance Certificate History

Certificate No: **CE 618037**

Date: **2020-03-19**

Issued To: **UWHM Sdn. Bhd.**
987,
Jalan Perindustrian Bukit Minyak 7, Mukim 13
Kawasan Perindustrian Bukit Minyak
Bukit Mertajam, SPT Penang
14000
Malaysia

Date	Reference Number	Action
28 July 2015	8195112	First issue.
22 February 2019	9676560	Name change from: UWC Healthcare Mfg (M) Sdn Bhd, to: UWHM SDN BHD. Blow moulding manufacturing process moved inhouse.
27 March 2019	8713579	Traceable to NB 0086.
19 March 2020	3142838	Certificate renewal UWHM Sdn. Bhd. address format amended to make it consistent across all certificates held. Sub-contractor address for Synergy Sterilisation (M) Sdn Bhd. amended to reflect format in their ISO 13485:2016 certificate
Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3		
07 July 2021	3477112	Addition of UWHM Sdn. Bhd. as a critical subcontractor for manufacture

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Inspiring trust for a more resilient world.

07 July 2021

UWHM Sdn. Bhd.
987,
Jalan Perindustrian Bukit Minyak 7, Mukim 13
Kawasan Perindustrian Bukit Minyak
Bukit Mertajam, SPT Penang
14000
Malaysia

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) and as per the guidance provided in MDCG 2020-3. The related MDD certificate specified below remains valid until the expiry date specified on the certificate.

Certificate	Directive and Annex	Reference Number	Changes approved
CE 618037	93/42/EEC Annex V	3477112	Addition of the critical subcontractor for manufacture: UWHM Sd. Bhd., PMT 790, Jalan Cassia Selatan 5/2, Taman Perindustrian Batu Kawan, Bandar Cassia, Pulau Pinang, 14110, Malaysia.

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Gary Slack
Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building
John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands

T: +31 20 346 0780
info.nl@bsigroup.com
bsigroup.nl

Declaration of Conformity

DoC Rev No: 08

Technical File No: UW-TF-01

Manufacturer	:	UWHM SDN. BHD PMT 790, Jalan Cassia Selatan 5/2, Taman Perindustrian Batu Kawan, Bandar Cassia, Pulau Pinang, 14110, Malaysia
EU Authorized Representative	:	*Obelis s.a.* Bd. General Wahis 53, 1030 Brussels, Belgium.
Product Brand	:	Hydrox
Medical Device (s) System	:	Prefilled Humidifier and Prefilled Humidifier with Macro Nebulization system
Classification	:	Class IIa, Rule 2
System Certificate	:	**Assessment Body - Standard (Certificate Number)** *BSI- ISO 13485:2016 (certificate #MD597859)* *BSI- ISO 9001: 2015 (certificate #FM605502)*
Standard Applied	:	*Council Directive 93/42/EEC* *EN ISO 13485: 2016* *EN ISO 14971:2016* *EN ISO 11137-1:2015* *EN ISO 11137-2:2015* *EN ISO 15223-1:2016* *ISO 11737-1: 2006* *ISO 11737-2:2009* *EN ISO 17665-1: 2006* *ISTA 2A*
Global Medical Device Nomenclature (GMDN)	:	35113 Humidifier, Non-heated.
Universal Medical Device Nomenclature System (UMDNS)	:	12051, Humidifier, Non-heated.
EC Certificate	:	**Notify Body (identification number) - Certificate Number** *BSI (2797) - CE 618037*

I hereby declare that Prefilled Humidifier and Prefilled Humidifier with Macro Nebulization system, Class IIa medical device is on the basis of examination of quality assurance system under requirements of Council Directive 93/42/EEC, Annex V. The device stated above has been designed to comply with the relevant sections of the standards mentioned above and applicable essential requirements of the Directives.

Authorised Signatory

JASON

.....

Name : Jason Ng Chin Aik

Position : Manufacturing Vice President

Date : 20 MAY 2022

Reference Number	Description
HA-30-000	300 mL Prefilled Humidifier with Adaptor
HA-35-000	350 mL Prefilled Humidifier with Adaptor
HA-40-000	400 mL Prefilled Humidifier with Adaptor
HA-45-000	450 mL Prefilled Humidifier with Adaptor
HA-50-000	500 mL Prefilled Humidifier with Adaptor
HA-55-000	550 mL Prefilled Humidifier with Adaptor
HA-60-000	600 mL Prefilled Humidifier with Adaptor
HA-65-000	650 mL Prefilled Humidifier with Adaptor

Reference Number	Description
NA-45-000	450 mL Prefilled Humidifier with Macro Nebulization System
NA-65-000	650 mL Prefilled Humidifier with Macro Nebulization System
NA-75-000	750 mL Prefilled Humidifier with Macro Nebulization System
NA-90-000	900 mL Prefilled Humidifier with Macro Nebulization System