

EG-Konformitätserklärung

EC-Declaration of Conformity déclaration CE de conformité

Wir, Löwenstein Medical SE &
Co.KG, Arzbacher Straße 80, 56130
Bad Ems, Deutschland erklären
unter unserer alleinigen
Verantwortung, dass folgendes
Produkt

We, Löwenstein Medical SE &
Co.KG, Arzbacher Strasse 80, 56130
Bad Ems, Germany declare under
our sole responsibility that the
following product:

Nous, Löwenstein Medical SE &
Co.KG, Arzbacher Strasse 80, 56130
Bad Ems, Allemagne déclarons
sous notre seule responsabilité fait
le produit suivant:

SRN DE-MF-000006028

Produktbeschreibung Atemgasanfeuchter / Humidifier
Product description / Descripción del producto

Produktname LM2000
Product Name / Nom du produit

Basic UDI - DI 426017127LM2000RY

Type	Artikelnummer Part Numbers / Référence	Klassifizierung Classification
LM2000 Neo (110V)	0217106neo	I Ib
LM2000 (230V)	0217105-1	I Ib
LM2000 Neo (230V)	0217105neo	I Ib
LM2000 (110V)	0217106	I Ib
LM2000 Neo (110V)	0217106-1	I Ib
LM2000 HomeCare	0217105	I Ib

die Anforderungen der Richtlinie
93/42/EWG über Medizinprodukte
erfüllt, nachgewiesen durch ein
Konformitätsbewertungsverfahren
nach Anhang II

complies with the requirements of
the Directive 93/42/EEC for Medical
Devices, confirmed by a conformity
assessment procedure based on
annex II

est conforme aux exigences de la
directive 93/42 / CEE relative aux
dispositifs médicaux, confirmés
par une procédure d'évaluation de
la conformité sur la base de
l'annexe II

Benannte Stelle / Notified Body / Organisme notifié
TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland



Gültigkeit:
Diese Konformitätserklärung ist
gültig für den Zeitraum des
EG-Zertifikates
Nr. HD 60146428 0001
(gültig bis 2024-05-26)

Validity: This declaration is valid for
the period given in the
EC-Certificate
No. HD 60146428 0001
(valid until 2024-05-26)

Validité: Cette déclaration de
conformité est valable pour la
période du certificat CE
No. HD 60146428 0001
(valable jusqu'au 2024-05-26)

Datum / Unterschrift
Date / Sign / Connexion

2021-12-03 Jens Schmidt

Funktion im Unternehmen
Function in the Company
Fonction dans l'entreprise

Qualitätsmanagement
Qualitymanagement Representative
Représentant Qualitymanagement

Zubehörliste

List of Accessoires

Liste des accessoires

Artikelnummer Part Numbers Référence	Produktname Product Name Nom du produit
a180v2c	breathing circuit,adult,1,80m, IV,heated (i+e),disposable,w/waterchamber
a180v1c	breathing circuit,adult,1,80m, IV,heated (i),disposable,w/waterchamber
a180v2	breathing circuit,adult,1,80m, IV,heated (i+e),disposable,w/o waterchamber
a180v1	breathing circuit,adult,1,80m, iv,heated (i),disposable,w/o waterchamber
a180nv1c	breathing circuit,adult,1,80m,NIV,heated(i),disposable,w/waterchamber
a180nv1c-ev	breathing circuit,adult,1,80m,NIV,heated (i),disposable,w/waterchamber,w/exhalationvalve
a180nv2c-pv	breathing circuit,adult,1,80m,NIV,heated (i),disposable,w/waterchamber,w/peepvalve
p180v2c	breathing circuit,paediatric,1,80m, iv,heated (i+e),disposable,w/waterchamber
p180v2	breathing circuit,paediatric,1,80m, iv,heated (i+e),disposable,w/o waterchamber
p180v1	breathing circuit,paediatric,1,80m, iv,heated (i),disposable,w/waterchamber
p180nv1c	breathing circuit,paediatric,1,80m,NIV,heated (i),disposable,w/waterchamber
n160v2c-rv	double heated (i+e), disposable breathing circuit for Neo, w/waterchamber incl Backpressurevalve, IV, length 1,60m + Incubatorext. 30 cm, Vti ≤ 50 ml
n160v2c	breathing circuit,neonatal,1,60m, iv,heated (i+e),disposable,w/waterchamber
n160v1c	breathing circuit,neonatal,1,60m, iv,heated (i),disposable,w/waterchamber
n160v2	breathing circuit,neonatal,1,60m, iv,heated (i+e),disposable,w/o waterchamber
n160v1	breathing circuit,neonatal,1,60m, iv,heated (i),disposable,w/o waterchamber
n160v2c-rv-1.1	double heated (i+e), disposable breathing circuit for Neo, w/waterchamber incl Backpressurevalve, transport HFO Circuit, IV, length 1,60m + Incubatorext. 30 cm, Vti ≤ 50 ml
n160v2c-rv-1	insp heated (i), disposable breathing circuit for Neo, w/waterchamber incl Backpressurevalve, HFO Circuit IV, length 1,60m + Incubatorext. 30 cm, Vti ≤ 50 ml
n160v1c-rv	insp heated (i), disposable breathing circuit for Neo, w/waterchamber incl Backpressurevalve, IV, length 1,60m + Incubatorext. 30 cm, Vti ≤ 50 ml
n160v1c-rv-1	insp heated (i), disposable breathing circuit for Neo, w/waterchamber incl Backpressurevalve, HFO Circuit IV, length 1,60m + Incubatorext. 30 cm, Vti ≤ 50 ml
n160v1c-rv-1.1	insp heated (i), disposable breathing circuit for Neo, w/waterchamber incl Backpressurevalve, transport HFO Circuit, IV, length 1,60m + Incubatorext. 30 cm, Vti ≤ 50 ml
n160v2c-rv-2	breathing circuit,neonatal,1,60m, iv,heated (i+e),disposable,w/waterchamber,w/flowsensor,w/expvalve
n160v1c-2	breathing circuit,neonatal,1,60m, iv,heated (i),disposable,w/waterchamber,w/flowsensor,w/expvalve
n160v2-2	breathing circuit,neonatal,1,60m, iv,heated (i+e),disposable, w/o waterchamber,w/flowsensor,w/expvalve
n160v1-2	insp heated (i), disposable breathing circuit for Neo, Flowsensor, Exp.-Valve, IV, length 1,60m + Incubatorext. 30 cm, Vti ≤ 50 ml
n160nv1c	breathing circuit,neonatal,1,60m,NIV,heated (i),disposable,w/waterchamber
n160nvb1c	breathing circuit,neonatal,1,60m,NIV,heated (i),disposable,w/waterchamber W/BubbleG
a150v2c	Double heated (i+e), disposable breathing circuit for Adult, w/waterchamber, IV, length 1,50m length, intended Vti≥ 300ml
a150v1c	Insp heated (i), disposable breathing circuit for Adult, w/waterchamber, IV, length 1,50m length, intended Vti≥ 300ml
a150nv1c	Insp heated (i), disposable breathing circuit for Adult, w/waterchamber, NIV, length 1,50m length, intended Vti≥ 300ml
a150nv1c-ev	Insp heated (i), disposable breathing circuit for Adult, w/waterchamber, exp.-valve, pressureline, NIV, length 1,50m length, intended Vti≥ 300ml
a150nv2c-pv	Insp heated (i), disposable breathing circuit for Adult, w/waterchamber, peep.-valve, pressureline, NIV, length 1.50m length, intended Vti≥ 300ml
a150v2	Double heated (i+e), disposable breathing circuit for Adult, wo/waterchamber, IV, length 1,50m length, intended Vti≥ 300ml
a150v1	Insp heated (i), disposable breathing circuit for Adult, wo/waterchamber, IV, length 1,50m length, intended Vti≥ 300ml
p150v2c	Double heated (i+e), disposable breathing circuit for Paed, w/waterchamber, IV, length 1,50m length, intended Vti≥ 50- 300ml
p150v1c	Insp heated (i), disposable breathing circuit for Paed, w/waterchamber, IV, length 1,50m length, intended Vti≥ 50- 300ml
p150nv1c	Insp heated (i), disposable breathing circuit for Ped, w/waterchamber, NIV, length 1,50m length, intended Vti≥ 50- 300ml

Artikelnummer Part Numbers Référence	Produktname Product Name Nom du produit
p150v2	Double heated (i+e), disposable breathing circuit for Paed, wo/waterchamber, IV, length 1,50m length, intended Vti≥ 50- 300ml
p150v1	Inspheated (i), disposable breathing circuit for Paed, wo/waterchamber, IV, length 1,50m length, intended Vti≥ 50- 300ml