

# 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 <small>Part Numbers / Référence</small>	Klassifizierung <small>Classification</small>
LM2000 Neo (110V)	0217106neo	Iib
LM2000 (230V)	0217105-1	Iib
LM2000 Neo (230V)	0217105neo	Iib
LM2000 (110V)	0217106	Iib
LM2000 Neo (110V)	0217106-1	Iib
LM2000 HomeCare	0217105	Iib

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