



**To Whom It May Concern
Certificate Exemption Customs Duties**

DONATION

We, the World Health Organization, certify that the goods covered by our order PO 202616138 for **MONTENEGRO** from the World Health Organization in Geneva are solely destined for the needs of the project and is

**A HUMANITARIAN AID DONATION
FROM THE WORLD HEALTH ORGANIZATION**

It has no commercial value. The value declared on the invoice is for Customs purposes only.

We would appreciate if the competent customs authorities could ensure a quick transit of the goods to the final destination.

These goods are consigned to:

ZU APOTEKE CRNE GORE MONTEFARM
LIUBLJANSKA BB. 81 000 PODGORICA
MONTENEGRO
Mr Raso DRAGAS
+38267620745
Montefarmcg@t-com.me

Value: USD 41,690.00





CERTIFICATE



This is to certify that the company

TNI medical AG

Hofmannstrasse 8
97084 Würzburg
Germany

has implemented and maintains a **Quality Management System**.

Scope:

Development and production of devices for vital parameter monitoring, respirators and oxygen therapy equipment, sleep medicine and ergospirometry

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

DIN EN ISO 13485 : 2016 + AC : 2017-07
EN ISO 13485 : 2016 + AC : 2016
ISO 13485 : 2016

Certificate registration no.	390773 MP2016
Certificate unique ID	170712310
Effective date	2018-10-26
Expiry date	2021-10-25
Frankfurt am Main	2018-10-26



DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

Konformitätserklärung

Declaration of Conformity



Wir, der Hersteller <i>We, the manufacturer</i>	TNI® medical AG Hofmannstraße 8 97084 Würzburg Germany
erklären in alleiniger Verantwortung, dass das Medizinprodukt mit seinem Zubehör (Anhang A) zur <i>declare under our sole responsibility that the medical device with its accessories (attachment A) to</i>	Therapie mit nasaler Insufflation mit der <i>Therapy with nasal insufflation with the</i> TNI softFlow-Gerätefamilie / -device family <i>in seinen Varianten/ in its variants</i> TNI softFlow 50 (Item-No: 40610021) TNI softFlow 50 (Item-No: 40610001) TNI softFlow 50 (Item-No: 40610200) (60l/min) TNI softFlow junior (Item-No: 40610071) TNI softFlow junior (Item-No: 40610051)
allen Anforderungen der Richtlinie 93/42/EWG und den anwendbaren harmonisierten Normen entspricht. <i>meets all the provisions of the directive 93/42/EEC and the applied harmonised standards.</i>	
Klassifizierung <i>Classification</i>	Ila Nach der Richtlinie 93/42/EWG Anhang IX, Regel 9 <i>According to the directive 93/42/EEC, Annex IX, rule 9</i>
Konformitätsbewertungs-Verfahren <i>Conformity Assessment Procedure</i>	Nach der Richtlinie 93/42/EWG Anhang II – ohne Abschnitt 4 <i>according to the directive 93/42/EEC, annex II – without paragraph 4</i>
Benannte Stelle/ <i>Notified Body</i> (nach / according to § 15 MPG)	DQS Medizinprodukte GmbH Deutsche Gesellschaft zur Zertifizierung von Management- Systemen für Medizinprodukte (CE ₀₂₉₇)
Gültig bis <i>Valid until</i>	2024-05-26

Würzburg, 2020-11-05

Ewald Anger

Vorstandsvorsitzender
Chief Executive Officer

Würzburg, 2020-11-05

Michael Siedler

Qualitätsmanagementbeauftragter
Quality Management Representative

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Anhang A / Attachment A

Tabelle 1 / Table 1: TNI softFlow-Gerätefamilie – Zubehör / -device family – accessories

Zubehörfamilie device family	Artikelbezeichnung article name	Artikelnummer item number
Allgemein General	TNI Gerätewagen „Marie“ TNI equipment cart „Marie“	30100028
	Ersatz Staubfilter 5 Stk. Dust Filter Reserves, 5 Pieces	40620060
	Schutzkappe Sauerstoffanschluss, weiß, 5 Stk. Protective Cap Oxygen Inlet, white, 5 Pieces	40620061
	Applikator Clip Applicator Clip	40630331
	Applikatorhalterung Applicator Headgear	40630334
	Stretchband, Applikatorhalterung, 1 Stück Stretchband, Applicator Headgear, 1 Piece	40630335
	Stretchband, Applikatorhalterung, 5 Stück Stretchband, Applicator Headgear, 5 Pieces	40630336
	SD-Karte (Fremdprodukt) SD-Card (third-party product)	40641103
	Sauerstoff-Sicherheitsschlauch, 4,0 m (Fremdprodukt) Oxygen Safety Tube (third-party product)	40641112
	PC Verbindungskabel, USB, 3 m PC connection cable, USB, 3m	40641113
	Staubfilterabdeckung Dust Filter Cover	40641117
	Netzkabel, 1,8 m, Eurostecker Power Cord, 1,8 m, Euro-Plug	40641150
	Netzkabel, 5 m, Eurostecker Power Cord, 5 m, Euro-Plug	40641153
Applikator Small Applicator Small	40630001 Klinik 40630101 Homecare	
Applikator Standard Applicator Standard	40630002 Klinik 40630102 Homecare	
Applikator Standard-Plus Applicator Standard-Plus	40630005 Klinik 40630105 Homecare	
Applikator Large Applicator Large	40630013 Klinik 40630113 Homecare	
Applikator Tracheal-Interface Applicator Tracheal-Interface	40630019 Klinik 40630119 Homecare	
Veoflo High Flow Tracheostomie, Schnittstelle (Fremdprodukt) Veoflo High Flow Tracheostomie, Interface (third-party product)	40630402	
Applicator X-Small, BC – Serie softFlow junior Applicator x-small, BC-series softFlow junior	40630123	
Applicator Small, BC – Serie softFlow junior Applicator small, BC-series softFlow junior	40630124	
Applicator Small-Plus, BC – Serie softFlow junior Applicator small-plus, BC-series softFlow junior	40630125	
NeoFlow nHFOT Nasenbrille Frühchen, Rot (Fremdprodukt) NeoFlow nHFOT Cannula Premature, Red (third-party product)	40630126	
NeoFlow nHFOT Nasenbrille Säuglinge, Hell Lila (Fremdprodukt) NeoFlow nHFOT Cannula Infant, Light Purple (third-party product)	40630128	
NeoFlow nHFOT Nasenbrille Kleinkinder, Dunkel Lila (Fremdprodukt) NeoFlow nHFOT Cannula Large Infant, Dark Purple (third-party prod.)	40630129	

Konformitätserklärung

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	NeoFlow nHFOT Nasenbrille Kinder, Grün (Fremdprodukt) NeoFlow nHFOT Cannula Pediatric, Green (third-party product)	40630130
	Innotube softFlow Innotube softFlow	40643606
	Applikator modul junior, softFlow junior ApplicatorModule junior, softFlow junior	40641115
	Temperaturmesselement, InnoTube softFlow Temperature Measuring Element, InnoTube softFlow	40641114
	NeoFlow Mütze Gr. XXS, bis 24 cm (Fremdprodukt) - NeoFlow Bonnet size XXS, up to 24 cm (third-party product)	40630340
	NeoFlow Mütze Gr. XS, 24 - 28 cm (Fremdprodukt) NeoFlow Bonnet size XS, 24 - 28 cm (third-party product)	40630341
	NeoFlow Mütze Gr. S, 28 - 31 cm (Fremdprodukt) NeoFlow Bonnet size S, 28 - 31 cm (third-party product)	40630342
	NeoFlow Mütze Gr. M, 31 - 34 cm (Fremdprodukt) NeoFlow Bonnet size M, 31 - 34 cm (third-party product)	40630343
	NeoFlow Mütze Gr. L, 34 - 38 cm (Fremdprodukt) NeoFlow Bonnet size L, 34 - 38 cm (third-party product)	40630344
	NeoFlow Mütze Gr. XL, 38 - 42 cm (Fremdprodukt) NeoFlow Bonnet size XL, 38 - 42 cm (third-party product)	40630345

Zubehörfamilie device family	Artikelbezeichnung article name	Artikelnummer item number
Klinik Clinic	Befeuchter Klinik-Hyglenset Humidifier Clinic Hygiene Set	40620040
	Befeuchtereinschub Klinik Humidifier Rack Clinic	40641107
	Luftbrücke Air Bridge	40641108
	Befeuchterkammer Auto-Fill (Fremdprodukt) Humidification Chamber (third-party product)	40641110
	Clear-Guard 3 Beatmungsfilter (Fremdprodukt) Clear-Guard 3 Breathing-Filter (third-party product)	40641111
Homecare Homecare	Befeuchter Homecare Humidifier Homecare	40620000
	Wasserbehälter Befeuchter Homecare Water Tank Humidifier Homecare	40641104
	Deckel Befeuchter Homecare Lid Humidifier Homecare	40641105
	Zykloneinsatz Befeuchter Homecare Cyclone Humidifier Homecare	40641106

PO 2427

28.01.2021 15:05:07



ZU APOTEKE CRNE GORE MONTEFARM

Ljubljanska bb PODGORICA

Matični broj: 02017105

PDV broj: 20/31-00073-7

Šifra djelatnosti: 052310

Ž.r.: 535-4918-69

510-205-07

530-12751-75

550-4768-38

Prva Banka Crne Gore
 Crnogorska Komercijalna Banka
 Nib Banka
 Podgorička Banka,

OTPREMNICA-FAKTURA

OTPREMNICA BROJ: 2021000072
 DATUM OTPREMNICE: 28.01.2021
 SKLADIŠTE: SKLADIŠTE DONACIJA
 BROJ TREBOVANJA:

KOMITENT: KLINIČKI CENTAR CG APOTEKA
 za magacin, donacija od SZO

Rbr	Šifra	Artikal / Šifra fonda	Rok	Seriya	Jm	Količina	Cijena	Rab%	PDV	Iznos
1	40347	Nazalni neinvazivni ventilator sa opremom TNI medical			pak	4.00	3,429.1300	100	7	.00

UKUPNI IZNOS RABATA: 13,716.52

UKUPNI IZNOS OSNOVICE: .00

UKUPNI IZNOS PDV-a: 0.00

UKUPNI IZNOS SA PDV-om: 0.00

Osnovica za PDV	Stopa PDV-a %	Iznos PDV-a
0.00	7	0.00

OPERATER:

KONTROLISAO:

RUKOVODILAC:

M.P.

ROBU PRIMIO:

Napomena: Nakon ovjerene otpremnice od strane komitenta, naknadne reklamacije se neće prihvatiti.