

UPS - TBS

Main Package Service Center

Waybill

25 SEP 2020

02
05



1Z0W9995DA36942085

Service Level: **28**

Worldwide Express Saver

Kolli: 1

Weight: 1.0 KGS

Shipper 0W9995

MEDSAN GMBH

BRANDSHOFER DEICH 10

20539 HAMBURG

DE GERMANY

Deliver To:

MINISTRY OF HEALTH

AKAKI TSERETELI AVE 121

0119 TBILISI

GE GEORGIA

14-Sep-20

15:38

Printed by MEX-TONI at Terminal: DESKTOP-NOV63 ESKTOP-NOV63



Konformitätserklärung

Declaration of Conformity

Produktbezeichnung / product name

MEDsan COVID-19 IgM/IgG Schnelltest

Gemäß der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostika ist MEDsan COVID-19 IgM/IgG Schnelltest ein IVD Medizinprodukt gemäß der oberen Richtlinie. Das Produkt ist weder in der Liste des Anhangs II A oder B der Richtlinie gelistet.

Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices the MEDsan COVID-19 IgM/IgG Rapid Test is an IVD medical device. Our product is not listed in neither list A nor B of Annex II of directive 98/79/EC.

Hersteller / Manufacturer

MPC International S.A. · 26, Boulevard Royal · L-2449 Luxembourg · Luxembourg

Händler / Dealer

MEDsan GmbH, Brandshofer Deich 10, D-20539 Hamburg

GMDN Code 48247

Erklärung / declaration

Wir erklären in alleiniger Verantwortung, dass das Medizinprodukt für die In-vitro-Diagnostik mit folgender Klassifizierung nach der Richtlinie über In-vitro-Diagnostika 98/79/EG Sonstiges Produkt allen anwendbaren Anforderungen der Richtlinie über In-vitro-Diagnostika 98/79/EG entspricht.

We declare under our sole responsibility that the above mentioned in vitro diagnostic medical device classified as follows according to the directive on in vitro diagnostic medical devices 98/79/EC as other device meets all the provisions of the directive on in vitro diagnostic medical devices 98/79/EC which apply to it.

Luxembourg, den 30.06.2020

Hans-Albert Schultz
MPC International S.A.
Hersteller / Manufacturer



gültig bis/valid till: 29.06.2021

MPC INTERNATIONAL S. A.
26, Boulevard Royal
L-2449 LUXEMBOURG
Tel. +352 22 99 99 55 46
Konformitätserklärung / Declaration of conformity
Seite/Page 1 von 1



FREE SALES CERTIFICATE / CERTIFICAT DE LIBRE VENTE

LU/IVD/FSC/5/2020

In vitro diagnostic medical devices covered by Directive 98/79/EC
Dispositifs médicaux de diagnostic in vitro couverts par la directive 98/79/CE

TO BE COMPLETED BY THE APPLICANT / A COMPLÉTER PAR LE DEMANDEUR

Device Trade Name / Nom commercial du dispositif MEDsan Covid-19 IgM/IgG Schnelltest	Device Identification / Identification du dispositif MEDsan Covid-19 IgM/IgG Schnelltest
Classification ☐ liste A ☐ liste B ☐ self-test/autotest ¹ ☒ other/autre	Notified body / Organisme notifié² Nr: TÜV Rheinland
Code GMDN: 48247	
Certificate(s) type(s) / Type(s) de certificat(s)² SX 60139342001, gültig bis 02.03.2021	Certificate(s)/Certificat(s)² Validity / Validité² N°: N°:
Manufacturer / Fabricant Name/Nom: MPC International S.A. Address / adresse: 26, Boulevard Royal L-2449 Luxembourg	Authorized representative / Mandataire³ Name/Nom: Address / adresse: N/A

I the undersigned declare that the above-mentioned information is correct and that the devices stated on the declarations and, where applicable, on the certificates of the notified body are CE marked under my responsibility within the meaning of Directive 98/79/EC and fulfil the essential requirements of health, safety and performance taking account of their intended purpose.

Je soussigné(e) déclare que les informations susmentionnées sont exactes et que les dispositifs figurant sur les déclarations CE de conformité et, le cas échéant, sur les certificats de l'organisme notifié sont marqué CE sous ma responsabilité au titre de la directive 98/79/EC et répondent aux exigences essentielles de santé, de sécurité et de performance en tenant compte de leur destination.

Name & Function / Nom & Fonction :

Address / Adresse⁴ :

Date: 11.5.2020

MPC INTERNATIONAL S. A.
26, Boulevard Royal
L-2449 LUXEMBOURG
Tel. +352 22 99 99 55 46
Fax +352 22 99 99 54 99
Signature

RESERVED FOR THE ADMINISTRATION / RÉSERVÉ À L'ADMINISTRATION

In vitro diagnostic medical devices bearing the CE marking indicate that they have been subject to an assessment of their conformity according with the relevant provisions of Directive 98/79/EC. These devices can be marketed in Luxembourg and, in other Member States of the EU, and be exported to non-EU Member States. This free sales certificate is valid until the maintenance, by the manufacturer / legal representative of the concerned medical device, of a declaration of conformity together with, where appropriate, the certificates delivered by a notified body. This free sale certificate can only be used for exportation outside the EU.

Les dispositifs médicaux de diagnostic in vitro portant le marquage CE indiquent qu'ils ont été soumis à une évaluation de leur conformité selon la directive 98/79/CE. Ces dispositifs peuvent être commercialisés au Luxembourg et dans les autres États membres de l'UE, et être exportés vers les pays tiers. Ce certificat de libre vente est valide à concurrence du maintien, par le fabricant / mandataire du dispositif médical concerné, d'une déclaration de conformité, accompagnée le cas échéant, de(s) certificat(s) nécessaire(s) délivré(s) par un organisme notifié. Ce certificat de libre vente est utilisable uniquement à des fins d'exportation hors UE.

Name & Function / Nom et fonction

Date: 26.4.2020

Dr Jean-Claude Schmit
Directeur de la Santé

Signature

- 1 Concerne les autotests hors annexe II de la directive 98/79/CE
- 2 Ne concerne pas les dispositifs en autocertification (pas d'implication de l'organisme notifié)
- 3 Les coordonnées du mandataire sont requises lorsque le fabricant n'est pas établi sur le territoire de l'UE.
- 4 Le siège social du demandeur se trouve sur le territoire du Grand-Duché de Luxembourg.

Invoice

FROM						
Tax ID/EIN/VAT No.: Contact Name: Kamila Tscheikina MEDsan GmbH Brandshofer Deich 10 Hamburg 20539 Germany (Federal Republic) Phone: 016096758724		Waybill Number: 0W9995F79TY Shipment ID: 0W9995F79TY  Date: 11/SEP/2020 Invoice No: PO No: Terms of Sale (Incoterm): Reason for Export: Sample				
SHIP TO		SOLD TO INFORMATION				
Tax ID/VAT No.: Contact Name: in Tbilisi Georgia Ministry of Health Akaki Tsereteli Ave 121 TBILISI 0119 Georgia Phone: 02080900428		Tax ID/VAT No.: Contact Name: in Tbilisi Georgia Ministry of Health Akaki Tsereteli Ave 121 TBILISI 0119 Georgia Phone: 02080900428				
Units	U/M	Description of Goods/Part No.	Harm. Code	C/T/O	Unit Value	Total Value
1	BOX	COVID-19 TEST KIT - "HUMANITARIAN AID" Medical Devices Sample shipment without commercial value COVID-19 TESTSET	30021500	DE	10,00	10,00

Additional Comments:

Declaration Statement:
All MEDsan medical products in this shipment were manufactured in Germany.

MEDsan GmbH
Brandshofer Deich 10 20539 Hamburg
Ship 040/38023838 Fax 040/228585699
Tel 040/38023838 info@medsan.eu

Date 11.09.20

Invoice Line Total:	10,00
Discount/Rebate:	0,00
Invoice Sub-Total:	10,00
Freight:	0,00
Insurance:	0,00
Other:	0,00
Total Invoice Amount:	10,00
Total Number of Packages: 1	Currency: EUR
Total Weight: 1.0 KGS	

MEDsan GmbH, Brandshofer Deich 10, 20539 Hamburg

Ministry Of Health in Tbilisi, Georgia
Akaki Tsereteli Ave 121
0119 TBILISI
GEORGIA

Delivery		
Document No.	Date	Page
81000954	9/11/2020	1 / 1
Customer No.	UID-Businesspartner	
20029	GB222494715	
Ref.	your order from 24.08.2020/ E-Mail	
Your contact	Innendienst	
Billing Address	Unit M19 Premier Business Centre Aftec Ltd. Unit M19 Premier Business Centre 47-49 Park Royal Road London NW10 7LQ UNITED KINGDOM	

Description	Quantity	UoM
-------------	----------	-----

Based on invoice 91000275 from 08/24/2020.

1 **MEDsan COVID-19 IgM/IgG Rapid Test** 25.00 pcs

Item Code: T00039

Test Device, Pipette, Buffer, Package insert, Safety Lancet, Alcohol Prep Pad.
HS-CODE/TARIC: 30021500

1x 25 Box

25 x Test Devices,
25 x Pipettes,
1 x Buffer,
1 x Package insert,
25 x Safety Lancets,
25 x Alcohol Prep Pad.

Declaration: All MEDsan medical products in this shipment were manufactured in Germany.

Shipping Method: EX WORKS

MEDsan GmbH
Brandshofer Deich 10
20539 Hamburg
Germany

Phone: 040/38023838
E-mail: info@medsan.eu
TAX Number: DE326098997

Bank Details: Deutsche Bank
Account Number: 248155400
Bank Code: 20070000
Swift/BIC Code: DEUTDEHHXXX
IBAN Code: DE43200700000248155400