CERERE DE PARTICIPARE

Către **IMSP Institutul Oncologic, mun.Chişinău str. N. Testemițanu 30**

Stimaţi domni,

Ca urmare a anunțului/invitației de participare/de preselecție apărut în Buletinul achizițiilor publice și/sau Jurnalul Oficial al Uniunii Europene, nr ocds-b3wdp1-MD-1664799119185 din 03/10/2022 (ziua/luna/anul), privind achiziționarea Consumabile medicale (diverse ace și măști pentru radioterapie) Repetat prin procedura de achiziție Achizitii de valoare mica (denumirea contractului de achiziție publică), noi Medist Grup SRL (denumirea/numele ofertantului/candidatului), am luat cunoștință de condițiile și de cerințele expuse în documentația de atribuire și exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavînd obiecții la documentația de atribuire.

Data completării 10.10.2022

Digitally signed by Anghel Gabriela-Cristina
Date: 2022.10.10 11:49:39 EEST
Reason: MoldSign Signature
Location: Moldova

Cu stimă,
Ofertant/candidat
Gabriela-Cristina Anghel
(semnătura autorizată)

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

DECLARAŢIE
privind valabilitatea ofertei

Către: **IMSP Institutul Oncologic, mun.Chişinău str. N. Testemițanu 30**

Stimaţi domni,

Ne angajăm să menţinem oferta valabilă, **privind achiziţionarea Consumabile medicale (diverse ace și măști pentru radioterapie) Repetat prin procedura de achiziție Achizitii de valoare mica** pentru o durată de 30 zile, (trei zeci), respectiv până la data de 16/11/2022 (ziua/luna/anul), şi ea va rămâne obligatorie pentru noi şi poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 10.10.2022

Cu stimă,
Ofertant/candidat
Gabriela-Cristina Anghel
(semnătura autorizată)

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chişinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

orfit Leader in thermoplastic innovations

EC – Declaration of Conformity

Manufacturers Name:	Orfit Industries N.V.
SRN (Single Registration Number):	BE-MF-000007872
Manufacturers Address:	Vosveld 9a, 2110 Wijnegem, Belgium
Basic UDI-DI:	5420028700214S
Name of the Device(s):	Raycast® High Precision - Efficast® Masks, Nanor Masks and Hybrid Masks with Nanor for Patient Immobilisation -Head, Neck and Shoulder
Product code(s):	35763/16MI, 35763/2MI, 35763/16MI/NH, 35763/16MI/EM, 35760/EFF16MI, 35760/EFF16MI/EM, 35779/16MI, 35763/16MI+N, 35763/2MA, 35763/2MA/NH, 35763/2MA/M, 35763/2MA/EM, 35760/EFF2MA, 35779/2MA, 35779/2MA/M, 35779/2MA/EM, 35764/16MI, 35764/2MA, 35764/2MA/NH, 35764/2MA/M, 35764/2MI+N, 33700/16MI, 33700/16MI/M, 33700/16MI/EM, 33700/2MA, 33700/2MA/M, 33700/2MA/EM, 33700/2MA/NH, 33730/4, 33700/2MI+N, 33710/2MA, 33688/2MA, 33705/2MA/NH, 33688/2MA, 33705/2MA, 33702/2MA, 33794/2MA, 33759/16MI/12MI+N, 33740/2MA/12MI+N, 33740/2MA/12MI+N/NH, 33737/2MA/12MI+N/NH, 33733/16MI/12MI+N, 33730/2MA/12MI+N, 33730/2MA/12MI+N/NH, 33730/2MA/12MI+N/G17, 33730/2MA/12MI+N/NH/G17, 33791/2MA/12MI+N, 33782/16MI/12MI+N, 33783/16MI/12MI+N, 33748/2MA/12MI+N/NH, 33749/2MA/12MI+N/NH, 33785/16MI/12MI+N, 33787/16MI/12MI+N, 33750/2MA/12MI+N/NH, 33776/2MA, 33776/32MA, 35763/16MI+N/NH, 33700/2MI+N/NH, 33735/16MI/12MI+N
Classification:	Class I, according the rules of Annex VIII
Conformity assessment route:	Orfit Industries N.V. uses the following procedures for the CE-labelling of their products according the Regulation MDR 2017/745: Class I: EC conformity declaration according to Annex IV.
Applied norms:	ISO 13485:2016 ISO 14971:2019 ISO 15223-1:2021 ISO 10993-5:2009 ISO 10993-10:2010

This declaration of conformity is issued under the sole responsibility of Orfit Industries N.V. We hereby declare that the medical device(s) specified above meet the provisions of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval ISO 13485:2016 issued by Lloyd's Register EMEA – LRQA.
All supporting documentation is retained at the premises of the manufacturer.

Eddy Marivoet,
Wijnegem, 9 December 2021

Quality Assurance & Regulatory Affairs Manager

Vosveld 9A | B-2110 Wijnegem | Belgium
T (+32) (0)3 326 20 26
welcome@orfit.com

Leader in thermoplastic innovations

EC – Declaration of Conformity

Manufacturers Name:	Orfit Industries N.V.
SRN (Single Registration Number):	Pending until EudaMed implementation
Manufacturers Address:	Vosveld 9a, 2110 Wijnegem, Belgium
Basic UDI-DI:	0542002870060MR
Name of the Device(s):	Raycast® High Precision – Masks for Extracranial Immobilization
Product code(s):	33715/2MA, 33716/2MA, 33717/2MA, 33775/2MI/12MI+N, 33683/32MA, 33723/32MA/L, 33723/32MA/R, 33724/32MA, 33788/2MI/12MI+N, 35790/2MA, 35727/32MA, 35728/32MA, 33778/32MA/NP, 35797/2MA/NP, 35788/32MA, 35787/32MA, 35784/32MA, 35780/32MA, 35710/2MA, 35711/32MA, 35712/32MA, 33774/2MA/12MI+N, 35792/32MA, 35793/32MA, 35794/2MI, 35795/2MI, 35796/2MI, 35799/2MI/L, 35799/2MI/R
Classification:	Class I, according the rules of Annex VIII
Conformity assessment route:	Orfit Industries N.V. uses the following procedures for the CE-labelling of their products according the Regulation MDR 2017/745: Class I: EC conformity declaration according to Annex IV.
Applied norms:	ISO 13485:2016 ISO 14971:2019 ISO 15223-1:2021 ISO 10993-5:2009 ISO 10993-10:2010

This declaration of conformity is issued under the sole responsibility of Orfit Industries N.V. We hereby declare that the medical device(s) specified above meet the provisions of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval ISO 13485:2016 issued by Lloyd's Register EMEA – LRQA.
All supporting documentation is retained at the premises of the manufacturer.

Eddy Marivoet,
Wijnegem, 10 August 2021

Quality Assurance & Regulatory Affairs Manager

www.orfit.com

ORFIT INDUSTRIES
Vosveld 9A | B-2110 Wijnegem | Belgium
T (+32) (0)3 326 20 26
welcome@orfit.com

Lloyd's Register

Current issue date: 10 September 2020
Expiry date: 9 September 2023
Certificate identity number: 10284725

Original approval(s):
ISO 13485 - 13 February 1996

Certificate of Approval

This is to certify that the Management System of:

Orfit Industries

Vosveld 9a, 2110 Wijnegem, Belgium

has been approved by Lloyd's Register to the following standards:

ISO 13485:2016

Approval number(s): ISO 13485 – 0016548

The scope of this approval is applicable to:

Design, development, manufacturing and sales of thermoformable polymeric products and accessories for orthoses, for prosthetic components and for patient immobilisation in radiation oncology.

Paul Graaf

Area Operations Manager North Europe

Issued by: Lloyd's Register Nederland B.V.

for and on behalf of: Lloyd's Register Quality Assurance Limited

UKAS MANAGEMENT SYSTEMS
001