CERERE DE PARTICIPARE

Către **IMSP IMSP Institutul Oncologic, mun.Chişinău str. N. Testemiţanu 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-1652940526440 din 19/05/2022 (ziua/luna/anul), privind achiziționarea Accesorii și consumabile pentru echipament medical radioterapeutic prin procedura de achiziție Cererea ofertelor de prețuri (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 26.05.2022

Digitally signed by Anghel Gabriela-Cristina
Date: 2022.05.26 15:02:10 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

ORDIN DE PLATA NR.255 Tip.doc. 1

DATA EMITERII: 25 mai 2022

PLATITI:5372-58 LEI: Cinci Mii Trei Sute Saptezeci si Doi, 58

PLATITOR: (R)MEDIST GRUP SRL CODUL IBAN:MD57VI022242600000269MDL
CODUL FISCAL:1018600004516

PRESTATORUL PLATITOR
B.C VictoriaBank S.A. s.26 Chisinau

BENEFICIAR:(R) I.M.S.P. INSTITUTUL ONCOLOGIC CODUL IBAN:MD94ML000000002251702316
CODUL FISCAL:1003600151023

PRESTATORUL BENEFICIAR
MICB

DESTINATIA PLATII: Garantia pentru oferta la procedura de achizitie publica nr. Achizitii.md ID 210567 48 si MTender ID ocds-b3wdp1-MD-1652940526440 din data de19.05.2022. Fara TVA.

NORMAL/URGENT:NO

L.S.

CODUL TRANZACTIEI:001

DATA PRIMIRII: _____

DATA EXECUTARII: _____

SEMNATURILE EMITENTULUI

_____
SEMNATURA PRESTATORULUI

«VICTORIABANK»
DIRECȚIA OPERAȚIUNI
25. MAI. 2022

MOTIVUL REFUZULUI L.Ș.

15:35:15 25 MAY 2022
Semnatura electronica:
Sp3dI13rxWCGa33oU1bQ1SDssRjmnEirhgt4zTNfF5CmVSRONR8KNNozJWI36D5X1kVijoLjpHbS
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DECLARAŢIE
privind valabilitatea ofertei

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

Stimaţi domni,

Ne angajăm să menţinem oferta valabilă, **privind achiziționarea Accesorii și consumabile pentru echipament medical radioterapeutic prin procedura de achiziție Cererea ofertelor de prețuri** pentru o durată de 60 zile, (şase zeci), respectiv până la data de 05/08/2022 (ziua/luna/anul), şi ea va rămâne obligatorie pentru noi şi poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 26.05.2022

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

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:	54200287003453
Name of the Device(s):	Raycast® High Precision – Base Plates
Product code(s):	32110/12, 32110/MR, 32111, 32113, 32113MR, 32117, 32117MR, 29105, 32130/12, 32130/MR, 32140/12, 32150/12, 32150-PED, 32150/3, 32150/HX, 32150/12, 32148, 29099, 32110/7, 32110/8, 32110/9, 32044, 35751N, 35754/6N, 32122, 32123, 32124, 35702/2, 35702/4, 32124/MR, 32110/MR, 32809, 32064, 32046, 32047, 32048
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 November 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

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:	54200287004252
Name of the Device(s):	Raycast® High Precision Accessories Head Supports regular density
Product code(s):	35758-MD, 35758ZF-MD, 35713-MD, 35713ZF-MD, 35714-MD, 35714ZF-MD, 32399-MD, 32702-MD, 32701-MD, 32706-MD
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

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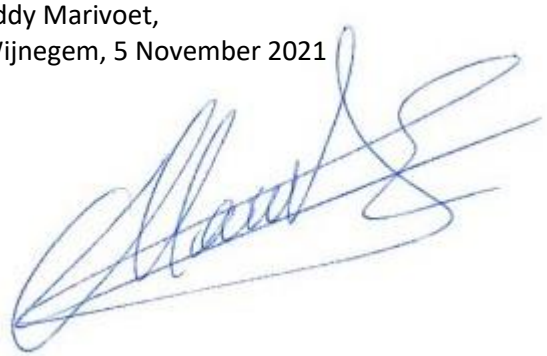
All supporting documentation is retained at the premises of the manufacturer.

Eddy Marivoet,
Wijnegem, 5 November 2021



Quality Assurance & Regulatory Affairs Manager

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:	54200287002552
Name of the Device(s):	MammoRX®
Product code(s):	CHB-1, CHO-1, CHT-1, CHS-1, CHD-1, CBA-1, CBS-2, 33170, 33176, 33177, 33178, 32145/5, 32145/6, CFB-001/EU, CFB-003/EU, CFB-004/EU, CFB-005/EU, CFB-006/EU, CFB-001, CFB-003, CFB-004, CFB-005, CFB-006, CFB-001/MR, CFB-003/MR, CFB-004/MR, CFB-005/MR, CFB-006/MR, CFB-001/EU/NG, CFB-003/EU/NG, CFB-004/EU/NG, CFB-005/EU/NG, CFB-006/EU/NG, 39320, 33177
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 November 2021

Quality Assurance & Regulatory Affairs Manager

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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:	5420028700485E
Name of the Device(s):	Raycast® High Precision Positioning Lung Board Solution
Product code(s):	29115
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, 5 November 2021

Quality Assurance & Regulatory Affairs Manager

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welcome@orfit.com

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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:	54200287003657
Name of the Device(s):	Raycast® High Precision - Base Plate-To-Couch Fixation Devices
Product code(s):	32181, 35744/6, 32000, 32001, 32002, 32045, 32066, 32070/17, 32126, 32151, 32154, 32160, 32165, 32165/6, 32166, 32191, 32207, 32208, 32209, 32317/16, 32810, 32813, 32814, 32815, 32816, 32817, 32822, 33106, 33109, 33119, 33167, 33168, 33173, 35744/6, 35747, 35747/4, 35747/6, 35747/8, 32063, 33219, 33218, 32197, 32172, 33220, 32077, 32165/2
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, 5 January 2022

Quality Assurance & Regulatory Affairs Manager

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:	5420028700295A
Name of the Device(s):	S.B.R.T. (Stereotactic Body Radiation Therapy Immobilisation System)
Product code(s):	32317/1, 32317/14, 32317/2, 32317/10, 32317/9, 32317/4, 32317/5, 32317/6, 32317/8, 32317/11, 32317/15, 32317/19, 32317/16, 32317/18, 32317/4/1, 32317/5/1, 32317/1/HX, 29029/SBRT, 32317/1/HX/2, 32317/23, 32317/26, 33149, 32317/28
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

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All supporting documentation is retained at the premises of the manufacturer.

Eddy Marivoet,
Wijnegem, 20 December 2021

Quality Assurance & Regulatory Affairs Manager

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welcome@orfit.com

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

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All supporting documentation is retained at the premises of the manufacturer.

Eddy Marivoet,
Wijnegem, 9 December 2021

Quality Assurance & Regulatory Affairs Manager

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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

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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
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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

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