Anexa nr. 1
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 1 din 21.07.2023

Solicitantul Oxivit Med SRL, cu sediul __mun.Chisinau bul. Decebal 82 ap.90 __, tel./fax: _+37368781333_, e-mail _oxivit.medical@gmail.com ,
solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

1. Freedom® Total Knee System™

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire de la Maxx orthopaedics Inc. catre Meril Life Science India PVT LTD
Scrisoare de imputernicire de la Meril Life Science India PVT LTD catre Oxivit-med SRL

Data 21.07.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Anexa nr. 2
La Procedurile administrative pentru notificarea
dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: Oxivit Med SRL, cu sediul mun.Chisinau bul. Decebal 82 ap.90, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1. Freedom® Total Knee System™

Sunt autentice și corespund realității.

Administrator: Kojevnikov Dmitrii *Semnătura* _____

Data 21.07.2023

To Whom So Ever It May Concern

MANUFACTURERS AUTHORIZATION

This is to certify and confirm that we Meril Life Science India PVT LTD. Bilakhia House, Survey No.135/139 Multanand Marg,Chala,Vapi – 396191, Gujarat,India, hereby confirms that **Oxivit-med SRL** is our Official business partner with business office at str. Decebal 82-90, Chisinau, Republic of Moldova, is been authorized by Meril Life Science India PVT LTD. to carry out the registration for all the Trauma and Orthopedics products manufactured and distributed by us.
This authorization is valid for 2years from the date of issuance and automatically renewable if no termination letter is issued.

Regards,

Mangrish. A
Meril Life Sciences India Pvt. Ltd.
Corporate office, Vapi.
T : +91 260 3052446

More to Life

maxx
orthopedics

Date: October 26, 2018

To,
Meril Life Sciences India Pvt. Ltd.
Bilakhia House, Survey No. 135/139,
Muktanand Marg, Chala, Vapi – 396191,
Gujarat, India

Sub: Authorization Letter

This is to certify that Meril Life Sciences India Pvt. Ltd. Bilakhia House, Survey No. 135/139, Muktanand Marg, Chala, Vapi – 396191, Gujarat, India is our authorized representative for our Orthopaedic range of devices to be registered and distributed globally.

Sincerely,

Ashesh Shah
Chief Executive Officer (CEO)
Maxx Orthopaedics Inc.

maxx orthopedics

DECLARATION OF CONFORMITY

I. **Manufacturer:** Maxx Orthopedics Inc., 2460 General Armistead Ave, Suite 100, Norristown, PA 19403, USA

II. **Authorized Representative:** AJW Consulting GmbH, Breite Straβe 3, 40213 Dusseldorf, Germany

III. **Quality System:** ISO 13485:2016 / NS EN ISO 13485:2016 (Certificate No. 272827-2018-AQ-IND-NA-PS)IS

IV. **Notified Body:** DNV AS, Veritasveien 3 1363 Hovik, Norvay. NB# 2460

V. **Classification:** Class III per MDD 2005/50/EC on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC as amended by 2007/47/EC

VI. **Conformity Assessment**: Annex II, including section 4

VII. **Rule**: Rule 8

VIII. **Product(s):** Freedom® Total Knee System™

IX. **GMDN Codes:** 46585 Tibial Insert
32831 Uncoated knee femur prothesis
32832 Uncoated knee tibia prosthesis, metallic
48066 Knee Stem
34199 Polyethylene patella prosthesis

X. **Certificates:** EC DESIGN EXAMINATION CERTIFICATE (No. 13123-2018-CE-IND-NA-PS)
EC-CERTIFICATE (No. 13122-2018-CE-IND-NA-PS)

We, the manufacturer, hereby declare that the medical devices, listed above conform to the applicable provisions of EC Directive 93/42/EEC Annex II, as amended by 2007/47/EEC concerning medical devices and we are solely responsible for their conformity.

Priscilla Herpai, Regulatory Manager 24Sep2021

Signature / Name / title Date

Part Number	Description	GMDN
UFCRLB00-K	Femoral Size B, CR, Left	32831
UFCRLC00-K	Femoral Size C, CR, Left	32831
UFCRLD00-K	Femoral Size D, CR, Left	32831
UFCRLE00-K	Femoral Size E, CR, Left	32831
UFCRLF00-K	Femoral Size F, CR, Left	32831
UFCRLG00-K	Femoral Size G, CR, Left	32831
UFCRLH00-K	Femoral Size H, CR, Left	32831
UFCRRB00-K	Femoral Size B, CR, Right	32831
UFCRRC00-K	Femoral Size C, CR, Right	32831
UFCRRD00-K	Femoral Size D, CR, Right	32831
UFCRRE00-K	Femoral Size E, CR, Right	32831
UFCRRF00-K	Femoral Size F, CR, Right	32831
UFCRRG00-K	Femoral Size G, CR, Right	32831
UFCRRH00-K	Femoral Size H, CR, Right	32831
UFPSLB00-K	Femoral Size B, PS, Left	32831
UFPSLC00-K	Femoral Size C, PS, Left	32831
UFPSLD00-K	Femoral Size D, PS, Left	32831
UFPSLE00-K	Femoral Size E, PS, Left	32831
UFPSLF00-K	Femoral Size F, PS, Left	32831
UFPSLG00-K	Femoral Size G, PS, Left	32831
UFPSLH00-K	Femoral Size H, PS, Left	32831
UFPSRB00-K	Femoral Size B, PS, Right	32831
UFPSRC00-K	Femoral Size C, PS, Right	32831
UFPSRD00-K	Femoral Size D, PS, Right	32831
UFPSRE00-K	Femoral Size E, PS, Right	32831
UFPSRF00-K	Femoral Size F, PS, Right	32831
UFPSRG00-K	Femoral Size G, PS, Right	32831
UFPSRH00-K	Femoral Size H, PS, Right	32831
RFPSLB00-RK	Stemmed Femoral Size B, PCK, Left	32831
RFPSLC00-RK	Stemmed Femoral Size C, PCK, Left	32831
RFPSLD00-RK	Stemmed Femoral Size D, PCK, Left	32831
RFPSLE00-RK	Stemmed Femoral Size E, PCK, Left	32831
RFPSLF00-RK	Stemmed Femoral Size F, PCK, Left	32831
RFPSLG00-RK	Stemmed Femoral Size G, PCK, Left	32831
RFPSLH00-RK	Stemmed Femoral Size H, PCK, Left	32831
RFPSRB00-RK	Stemmed Femoral Size B, PCK, Right	32831
RFPSRC00-RK	Stemmed Femoral Size C, PCK, Right	32831
RFPSRD00-RK	Stemmed Femoral Size D, PCK, Right	32831
RFPSRE00-RK	Stemmed Femoral Size E, PCK, Right	32831
RFPSRF00-RK	Stemmed Femoral Size F, PCK, Right	32831
RFPSRG00-RK	Stemmed Femoral Size G, PCK, Right	32831
RFPSRH00-RK	Stemmed Femoral Size H, PCK, Right	32831
ALCRXB209-K	All Poly Tibial Liner CR, Size B2 9mm	46585
ALCRXB211-K	All Poly Tibial Liner CR, Size B2 11mm	46585
ALCRXB214-K	All Poly Tibial Liner CR, Size B2 14mm	46585
ALCRXB217-K	All Poly Tibial Liner CR, Size B2 17mm	46585

ALCRXB220-K	All Poly Tibial Liner CR, Size B2 20mm	46585
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ALCRXG711-K	All Poly Tibial Liner CR, Size G7 11mm	46585
ALCRXG714-K	All Poly Tibial Liner CR, Size G7 14mm	46585
ALCRXG717-K	All Poly Tibial Liner CR, Size G7 17mm	46585
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UPUUX828-K	Patella, 28mm	34199
UPUUX831-K	Patella, 31mm	34199
UPUUX834-K	Patella, 34mm	34199
UPUUX837-K	Patella, 37mm	34199
UPUUX840-K	Patella, 40mm	34199
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MLPSXF717-K	Tibial Liner PS, Size F7-8 17mm	46585
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MLPSXG511-K	Tibial Liner PS, Size G5-6 11mm	46585
MLPSXG514-K	Tibial Liner PS, Size G5-6 14mm	46585
MLPSXG517-K	Tibial Liner PS, Size G5-6 17mm	46585
MLPSXG709-K	Tibial Liner PS, Size G7-8 9mm	46585
MLPSXG711-K	Tibial Liner PS, Size G7-8 11mm	46585
MLPSXG714-K	Tibial Liner PS, Size G7-8 14mm	46585
MLPSXG717-K	Tibial Liner PS, Size G7-8 17mm	46585
MLPSXH709-K	Tibial Liner PS, Size H7-8 9mm	46585
MLPSXH711-K	Tibial Liner PS, Size H7-8 11mm	46585
MLPSXH714-K	Tibial Liner PS, Size H7-8 14mm	46585
MLPSXH717-K	Tibial Liner PS, Size H7-8 17mm	46585
RLPSXB111-RK	Tibial Liner PCK, Size B1-2 11mm	46585
RLPSXB114-RK	Tibial Liner PCK, Size B1-2 14mm	46585
RLPSXB117-RK	Tibial Liner PCK, Size B1-2 17mm	46585
RLPSXB120-RK	Tibial Liner PCK, Size B1-2 20mm	46585
RLPSXB123-RK	Tibial Liner PCK, Size B1-2 23mm	46585
RLPSXB127-RK	Tibial Liner PCK, Size B1-2 27mm	46585
RLPSXB131-RK	Tibial Liner PCK, Size B1-2 31mm	46585
RLPSXC111-RK	Tibial Liner PCK, Size C1-2 11mm	46585
RLPSXC114-RK	Tibial Liner PCK, Size C1-2 14mm	46585
RLPSXC117-RK	Tibial Liner PCK, Size C1-2 17mm	46585
RLPSXC120-RK	Tibial Liner PCK, Size C1-2 20mm	46585
RLPSXC123-RK	Tibial Liner PCK, Size C1-2 23mm	46585
RLPSXC127-RK	Tibial Liner PCK, Size C1-2 27mm	46585
RLPSXC131-RK	Tibial Liner PCK, Size C1-2 31mm	46585
RLPSXC311-RK	Tibial Liner PCK, Size C3-4 11mm	46585
RLPSXC314-RK	Tibial Liner PCK, Size C3-4 14mm	46585
RLPSXC317-RK	Tibial Liner PCK, Size C3-4 17mm	46585
RLPSXC320-RK	Tibial Liner PCK, Size C3-4 20mm	46585
RLPSXC323-RK	Tibial Liner PCK, Size C3-4 23mm	46585

RLPSXC327-RK	Tibial Liner PCK, Size C3-4 27mm	46585
RLPSXC331-RK	Tibial Liner PCK, Size C3-4 31mm	46585
RLPSXD111-RK	Tibial Liner PCK, Size D1-2 11mm	46585
RLPSXD114-RK	Tibial Liner PCK, Size D1-2 14mm	46585
RLPSXD117-RK	Tibial Liner PCK, Size D1-2 17mm	46585
RLPSXD120-RK	Tibial Liner PCK, Size D1-2 20mm	46585
RLPSXD123-RK	Tibial Liner PCK, Size D1-2 23mm	46585
RLPSXD127-RK	Tibial Liner PCK, Size D1-2 27mm	46585
RLPSXD131-RK	Tibial Liner PCK, Size D1-2 31mm	46585
RLPSXD311-RK	Tibial Liner PCK, Size D3-4 11mm	46585
RLPSXD314-RK	Tibial Liner PCK, Size D3-4 14mm	46585
RLPSXD317-RK	Tibial Liner PCK, Size D3-4 17mm	46585
RLPSXD320-RK	Tibial Liner PCK, Size D3-4 20mm	46585
RLPSXD323-RK	Tibial Liner PCK, Size D3-4 23mm	46585
RLPSXD327-RK	Tibial Liner PCK, Size D3-4 27mm	46585
RLPSXD331-RK	Tibial Liner PCK, Size D3-4 31mm	46585
RLPSXE311-RK	Tibial Liner PCK, Size E3-4 11mm	46585
RLPSXE314-RK	Tibial Liner PCK, Size E3-4 14mm	46585
RLPSXE317-RK	Tibial Liner PCK, Size E3-4 17mm	46585
RLPSXE320-RK	Tibial Liner PCK, Size E3-4 20mm	46585
RLPSXE323-RK	Tibial Liner PCK, Size E3-4 23mm	46585
RLPSXE327-RK	Tibial Liner PCK, Size E3-4 27mm	46585
RLPSXE331-RK	Tibial Liner PCK, Size E3-4 31mm	46585
RLPSXE511-RK	Tibial Liner PCK, Size E5-6 11mm	46585
RLPSXE514-RK	Tibial Liner PCK, Size E5-6 14mm	46585
RLPSXE517-RK	Tibial Liner PCK, Size E5-6 17mm	46585
RLPSXE520-RK	Tibial Liner PCK, Size E5-6 20mm	46585
RLPSXE523-RK	Tibial Liner PCK, Size E5-6 23mm	46585
RLPSXE527-RK	Tibial Liner PCK, Size E5-6 27mm	46585
RLPSXE531-RK	Tibial Liner PCK, Size E5-6 31mm	46585
RLPSXF311-RK	Tibial Liner PCK, Size F3-4 11mm	46585
RLPSXF314-RK	Tibial Liner PCK, Size F3-4 14mm	46585
RLPSXF317-RK	Tibial Liner PCK, Size F3-4 17mm	46585
RLPSXF320-RK	Tibial Liner PCK, Size F3-4 20mm	46585
RLPSXF323-RK	Tibial Liner PCK, Size F3-4 23mm	46585
RLPSXF327-RK	Tibial Liner PCK, Size F3-4 27mm	46585
RLPSXF331-RK	Tibial Liner PCK, Size F3-4 31mm	46585
RLPSXF511-RK	Tibial Liner PCK, Size F5-6 11mm	46585
RLPSXF514-RK	Tibial Liner PCK, Size F5-6 14mm	46585
RLPSXF517-RK	Tibial Liner PCK, Size F5-6 17mm	46585
RLPSXF520-RK	Tibial Liner PCK, Size F5-6 20mm	46585
RLPSXF523-RK	Tibial Liner PCK, Size F5-6 23mm	46585
RLPSXF527-RK	Tibial Liner PCK, Size F5-6 27mm	46585
RLPSXF531-RK	Tibial Liner PCK, Size F5-6 31mm	46585
RLPSXF711-RK	Tibial Liner PCK, Size F7-8 11mm	46585
RLPSXF714-RK	Tibial Liner PCK, Size F7-8 14mm	46585
RLPSXF717-RK	Tibial Liner PCK, Size F7-8 17mm	46585

RLPSXF720-RK	Tibial Liner PCK, Size F7-8 20mm	46585
RLPSXF723-RK	Tibial Liner PCK, Size F7-8 23mm	46585
RLPSXF727-RK	Tibial Liner PCK, Size F7-8 27mm	46585
RLPSXF731-RK	Tibial Liner PCK, Size F7-8 31mm	46585
RLPSXG511-RK	Tibial Liner PCK, Size G5-6 11mm	46585
RLPSXG514-RK	Tibial Liner PCK, Size G5-6 14mm	46585
RLPSXG517-RK	Tibial Liner PCK, Size G5-6 17mm	46585
RLPSXG520-RK	Tibial Liner PCK, Size G5-6 20mm	46585
RLPSXG523-RK	Tibial Liner PCK, Size G5-6 23mm	46585
RLPSXG527-RK	Tibial Liner PCK, Size G5-6 27mm	46585
RLPSXG531-RK	Tibial Liner PCK, Size G5-6 31mm	46585
RLPSXG711-RK	Tibial Liner PCK, Size G7-8 11mm	46585
RLPSXG714-RK	Tibial Liner PCK, Size G7-8 14mm	46585
RLPSXG717-RK	Tibial Liner PCK, Size G7-8 17mm	46585
RLPSXG720-RK	Tibial Liner PCK, Size G7-8 20mm	46585
RLPSXG723-RK	Tibial Liner PCK, Size G7-8 23mm	46585
RLPSXG727-RK	Tibial Liner PCK, Size G7-8 27mm	46585
RLPSXG731-RK	Tibial Liner PCK, Size G7-8 31mm	46585
RLPSXH711-RK	Tibial Liner PCK, Size H7-8 11mm	46585
RLPSXH714-RK	Tibial Liner PCK, Size H7-8 14mm	46585
RLPSXH717-RK	Tibial Liner PCK, Size H7-8 17mm	46585
RLPSXH720-RK	Tibial Liner PCK, Size H7-8 20mm	46585
RLPSXH723-RK	Tibial Liner PCK, Size H7-8 23mm	46585
RLPSXH727-RK	Tibial Liner PCK, Size H7-8 27mm	46585
RLPSXH731-RK	Tibial Liner PCK, Size H7-8 31mm	46585
MTUUX100-K	Tibial Base Plate Size 1	32832
MTUUX200-K	Tibial Base Plate Size 2	32832
MTUUX300-K	Tibial Base Plate Size 3	32832
MTUUX400-K	Tibial Base Plate Size 4	32832
MTUUX500-K	Tibial Base Plate Size 5	32832
MTUUX600-K	Tibial Base Plate Size 6	32832
MTUUX700-K	Tibial Base Plate Size 7	32832
MTUUX800-K	Tibial Base Plate Size 8	32832
RTUUX100-RK	Stemmed Tibial Base Plate Size 1	32832
RTUUX200-RK	Stemmed Tibial Base Plate Size 2	32832
RTUUX300-RK	Stemmed Tibial Base Plate Size 3	32832
RTUUX400-RK	Stemmed Tibial Base Plate Size 4	32832
RTUUX500-RK	Stemmed Tibial Base Plate Size 5	32832
RTUUX600-RK	Stemmed Tibial Base Plate Size 6	32832
RTUUX700-RK	Stemmed Tibial Base Plate Size 7	32832
RTUUX800-RK	Stemmed Tibial Base Plate Size 8	32832
RJPSX400-RK	Offset Junction 4mm	48066
RJPSX600-RK	Offset Junction 6mm	48066
RSUU2075-RK	Stem Extension 7.5x75mm	48066
RSUU3075-RK	Stem Extension 7.5x100mm	48066
RSUU4075-RK	Stem Extension 7.5x150mm	48066
RSUU1090-RK	Stem Extension 9x40mm	48066

RSUU2090-RK	Stem Extension 9x75mm	48066
RSUU3090-RK	Stem Extension 9x100mm	48066
RSUU4090-RK	Stem Extension 9x150mm	48066
RSUU2105-RK	Stem Extension 10.5x75mm	48066
RSUU3105-RK	Stem Extension 10.5x100mm	48066
RSUU4105-RK	Stem Extension 10.5x150mm	48066
RSUU1120-RK	Stem Extension 12x40mm	48066
RSUU2120-RK	Stem Extension 12x75mm	48066
RSUU3120-RK	Stem Extension 12x100mm	48066
RSUU4120-RK	Stem Extension 12x150mm	48066
RSUU2135-RK	Stem Extension 13.5x75mm	48066
RSUU3135-RK	Stem Extension 13.5x100mm	48066
RSUU4135-RK	Stem Extension 13.5x150mm	48066
RSUU1150-RK	Stem Extension 15x40mm	48066
RSUU2150-RK	Stem Extension 15x75mm	48066
RSUU3150-RK	Stem Extension 15x100mm	48066
RSUU4150-RK	Stem Extension 15x150mm	48066
RSUU2165-RK	Stem Extension 16.5x75mm	48066
RSUU3165-RK	Stem Extension 16.5x100mm	48066
RSUU4165-RK	Stem Extension 16.5x150mm	48066
RAUUX000-RK	Tibial Augment Size 0	32832
RAUUX100-RK	Tibial Augment Size 1	32832
RAUUX200-RK	Tibial Augment Size 2	32832
RAUUX300-RK	Tibial Augment Size 3	32832
RAUUX400-RK	Tibial Augment Size 4	32832
RAUUX500-RK	Tibial Augment Size 5	32832
RAUUX600-RK	Tibial Augment Size 6	32832
RAUUX700-RK	Tibial Augment Size 7	32832
RAUUX800-RK	Tibial Augment Size 8	32832
RGPSDB00-RK	Distal Femoral Augment Size B	32831
RGPSDC00-RK	Distal Femoral Augment Size C	32831
RGPSDD00-RK	Distal Femoral Augment Size D	32831
RGPSDE00-RK	Distal Femoral Augment Size E	32831
RGPSDF00-RK	Distal Femoral Augment Size F	32831
RGPSDG00-RK	Distal Femoral Augment Size G	32831
RGPSDH00-RK	Distal Femoral Augment Size H	32831
RGPSPB00-RK	Posterior Femoral Augment Size B	32831
RGPSPC00-RK	Posterior Femoral Augment Size C	32831
RGPSPD00-RK	Posterior Femoral Augment Size D	32831
RGPSPE00-RK	Posterior Femoral Augment Size E	32831
RGPSPF00-RK	Posterior Femoral Augment Size F	32831
RGPSPG00-RK	Posterior Femoral Augment Size G	32831
RGPSPH00-RK	Posterior Femoral Augment Size H	32831
RRUUX407-RK	Augment Screw 7mm	32831
RRUUX412-RK	Augment Screw 12mm	32831
RRUUX417-RK	Augment Screw 17mm	32831

XI. **List of Standards:**

Document Number	Title	Edition / Date of Issue
ISO 13485	Medical devices – Quality management systems – Requirements for regulatory purposes	2012+AC:2012
EN ISO 14971	Medical devices – Application of Risk Management	2012
ISO 11135	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices. (Sterility)	2007
ISO 10993-1	Biological evaluation of medical devices -- Part 1: Evaluation and testing	2009
ISO 10993-7	Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals	2008
ISO 10993-17	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	2009
EN 1041	Information supplied by the manufacturer with medical devices	2008
ISO 13781	Poly (L-lactide) resins and fabricated forms of surgical implants – in vitro degradation testing	1997
ISO 14630	Non-active surgical implants – general requirements	1997
ISO/TR 13425	Guidelines for the selection of statistical methods in standardization and specification	2003
ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)	2009
ISO 11601-2	Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes.	2006
EN 556-1	Sterilization of medical devices – Requirements for medical devices to be designated “STERILE” – Part 1: Requirements for terminally sterilized medical devices.	2001/AC:2006
EN ISO 11138-2	Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization process	2009
ISO 11137-3	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects	2006
ISO 11137-1	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2007
ISO 14155-1	Clinical investigation of medical devices for human subjects - Part 1: General requirements	2009

REVISION LOG for DOC

Rev	Description	Date
New	Original Release	1/8/2010
A	Update Format of DOC	2/7/2011
B	Update to include stemmed tibia components and new address	8/4/2011
C	Update to reference current standard revisions	8/6/2012
D	Update to include Freedom PCK Components	5/14/2013
E	Update to remove sterilization statement and update Standards	05/05/2014
F	Update to include additional catalog numbers	10-FEB-2015
G	Update to include correct DQS address	03/15/2015
H	Update to reflect correct version of 13485 and Classification	05/06/2015
I	Update to remove Taper Set Screw and Plug, Central Plug, Liner Securing Pin, Augment Hole Plug	07-OCT-2015
J	Update GDMN codes; add EC CERTIFICATES and expiration dates; add doc# and ECO#	26-JAN-2018
K	Update format of DOC-001	05-FEB-2019
L	Update EC representative information	29-MAR-2019
M	Update EC Rep address, add MDR requirements	24-SEP-2021

EC Design Examination Certificate

Certificate No.:
13123-2018-CE-IND-NA-PS

Project No.:
PRJC-549027-2016-PRC-IND

Valid Until:
15 October 2023

This is to certify that:

Freedom® – Total Knee System

Manufactured by:

Maxx Orthopedics Inc

2460 General Armistead Ave., Ste. 100, Norristown, PA 19403, USA

Has been assessed with respect to:

Examination of the design of the product as described in Annex II section 4 of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 15 October 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

EC Design Examination Certificate

Certificate No.:
13123-2018-CE-IND-NA-PS

Project No.:
PRJC-549027-2016-PRC-IND

Valid Until:
15 October 2023

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as “Forskrift om Medisinsk Utstyr” by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	2018-10-15

Products covered by this Certificate:

Type of medical device and identification no.:	**Medical Device Class:**	**GMDN code:**
Freedom® – Total Knee System	III	

Short description of the Medical Device:

Freedom® Total Knee System consists of the following components:

Primary Knee Components

- Femoral Knee Component CR & PS (Left & Right),
- Tibial Base Plate,
- Tibial Articular Surface (liner Metal backed) CR & PS
- Patellar component
- All Poly Tibial Component (CR & PS)

Revision Knee Components

Stemmed Femoral Component

- PCK Femoral
- PCK Liner
- Femoral Augment – Distal & Posterior

Stemmed Tibial Component

- Stemmed tibial base plate
- Stem Extension
- Offset Junction
- Tibial Augment

The femoral component is offered in both cruciate retaining and posterior stabilizing designs. The femoral components are available in right and left configurations, and is available in sizes designated as B to H, to accommodate varying anatomy. Device components are for cemented use. The components are ETO and gamma sterilized.

EC Design Examination Certificate

Certificate No.:
13123-2018-CE-IND-NA-PS

Project No.:
PRJC-549027-2016-PRC-IND

Valid Until:
15 October 2023

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall inform Presafe of any intended change of the products detailed above and Presafe will assess the changes and decide if the certificate remains valid.

The following may render this Certificate invalid:

- Changes in the design of the products to which this Certificate refers.
- Changes in requirements of the scheme to which this Certificate refers.

Conformity declaration and marking of product

This Certificate must be accompanied with a valid EC Certificate Full Quality Assurance System.

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

EC Certificate
Full Quality Assurance System

Certificate No.:
13122-2018-CE-IND-NA-PS

Project No.:
PRJC-549027-2016-PRC-IND

Valid Until:
15 October 2023

This is to certify that the quality system of:

Maxx Orthopedics Inc
2460 General Armistead Ave., Ste. 100, Norristown, PA 19403, USA

For design, production and final product inspection/testing of:

Freedom® – Total Knee System

Has been assessed with respect to:

The conformity assessment procedure described in Annex II of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 15 October 2018

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL PRESAFE AS

Cathrine Wisbech

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.:
13122-2018-CE-IND-NA-PS

Project No.:
PRJC-549027-2016-PRC-IND

Valid Until:
15 October 2023

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
	Original Certificate	2018-10-15

Products covered by this Certificate:

Product Description	Product Name	Class
Freedom® – Total Knee System	Freedom™ Knee system consisting of the following components (Size designations: B to H) **Primary Knee Components:** **1. Femoral Component** • Cemented Femoral - CR and PS (Left & Right) **2. Metal backed Tibial Component** • Tibial Liner (UHMWPE) – CR and PS • Tibial Base plate **3. All – Poly tibial component** • All poly (UHMWPE) tibial component – CR & PS **4. Patellar Component** • UHMWPE Patella **Revision Knee Components:** **1. Stemmed Femoral Component** • PCK Femoral • PCK Liner	III*

	• Femoral Augment – Distal & Posterior **2. Stemmed Tibial Component** • Stemmed tibial base plate • Stem Extension • Offset Junction • Tibial Augment **3. Accessories** • Augment Screw • Taper set Screw • Liner Securing pin • Central Sealing Plug • Tibial Augment Hole Plug • Taper Hole Plug	

* Design assessment is covered by a separate EC-Design Examination Certificate No.: 13123-2018-CE-IND-NA-PS

Sites covered by this certificate

Site Name	Address
Maxx Orthopedics Inc	2460 General Armistead Ave., Ste. 100, Norristown, PA 19403, USA

EU Representative

RMS UK LTD., 28, Trinity Road, Nailsea, Somerset BS 484NU, UK

EC Certificate
Full Quality Assurance System

Certificate No.:
13122-2018-CE-IND-NA-PS

Project No.:
PRJC-549027-2016-PRC-IND

Valid Until:
15 October 2023

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
272827-2018-AQ-IND-NA-PS

Initial certification date:
09 October 2018

Valid:
09 October 2018 – 09 October 2024

This is to certify that the management system of

Maxx Orthopedics Inc

2460 General Armistead Ave., Ste. 100, Norristown, PA, 19403, USA

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, Manufacturing,Sales of Sterile Orthopaedic Implants and Reusable Surgical Instruments

Place and date:
Høvik, 05 January 2022

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 3, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative