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 19.10.2023

Solicitantul SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău
(adresa)
Tel./Fax: .+373-22-808517, +373-22-808719, fax +373-22-808519, e-mail biosistem.mld@gmail.com; info@biosistem-mld.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:

- Proteze necimentate de sold, model LATITUD (tija, cupa, cap, insert, suruburi, cupa bipolara)

Se anexează următoarele acte:
Declaraţie pe proprie răspundere
CE certificate
Declaratie de conformitate
Scrisoare de imputernicire

Digitally signed by Poiata Vitalie
Date: 2023.10.19 10:05:24 EEST
Reason: MoldSign Signature
Location: Moldova

Data 19.10.2023 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 dețin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: SRL Biosistem mld, cu sediul str. Albișoara 16/1 of.7, or. Chișinău, 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:

- Proteze necimentate de sold, model LATITUD (tija, cupa, cap, insert, suruburi, cupa bipolara)

Sunt autentice și corespund realității.

Administrator: Poiata Vitalie *Semnătura* _____

Data 19.10.2023

Date: 18th Oct 2023

To Whom So Ever It May Concern

This is to state that we Meril Health Care Pvt. Ltd an Orthopedic Implants manufacturing company based out at , Third floor, E-1-E-3, Meril Park, Survey No. 135 / B & 174 / 2, Mukanand Marg, Chala, Vapi Gujarat India— 396191 under the Manufacturing Licence Mfg. Lic. No : MFG/MD/2018/000027.
Hereby assign SRL Biosistem mld, as our Authorized representative based out in Republic of Moldova, mun. Chisinau, str. Albișoara 16/1 of.7, or. Chișinău,
As the authorized representative in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC or 90/385/EEC.
We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical device.

Best Regards
Mangrish. A
Meril HealthCare Pvt. Ltd.
Corporate office, Vapi.
T : +91 260 3052446

Meril

Healthcare

DECLARATION OF CONFORMITY

Document No. MH/DOC/060 Rev.03

Manufacturer's Name:	**MERIL HEALTHCARE PVT. LTD.**
Manufacturer's Address:	Ground & First Floor, Survey N0. 173/4 and First Floor, H1-H3, Meril Park, Survey No.135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat India
Product Name:	Latitud™ Hip Replacement system – Proximally Coated Uncemented Femoral Stem
Product Details:	GMDN code: 33181 Product code/ Part No.: _____ Batch No.: _____ Mfg. Date : _____ Expiry Date: _____

We, the manufacturer, hereby declare under sole responsibility that the medical above devices, conform to the applicable provisions of EC Directive 93/42/EEC Annex II, as amended by 2007/47/EEC concerning medical devices. All supporting documentation is retained under premise of manufacturer.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2012, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 10993-1:2018, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN 20417:2021, ISO 14644-1:2015, ISO 14644-2:2015, ASTM F 1980:2016, MDD/93/42/EEC:2007, EN ISO 14630:2012, EN ISO 21534:2009, EN ISO 21535:2009, ASTM F136:2013, EN ISO 5832-3:2016, ISO 13779-2:2018
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, excluding section 4
Device Classification:	Class III as per COMMISSION DIRECTIVE 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices.
Authorized Representative:	Obelis S.A., Bd. Général Wahis 53, 1030 Brussels, Belgium Tel: +32. 2. 732. 59. 54 Fax: +32. 2. 732. 60. 03 E-mail: mail@obelis.net
Quality System:	EN ISO 13485:2016/DIN EN ISO 13485:2016 (Certificate No.: Q5 105566 0001 Rev. 01 Valid till: 5 April 2026).
CE Certificate:	CE Certificate No.: 2195-MED-2106201 Valid till: 26 May 2024
Notifying Body:	Szutest Tatlisu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul Tel : + 90 216469 46 66
Notifying Body Number:	2195
Signature:	
Name:	Umesh Sharma
Designation:	GM-QA/RA
Date/Location:	**Date:24-04-2023** Location: Vapi, Gujarat, INDIA

Meril
Healthcare

DECLARATION OF CONFORMITY

Document No. MH/DOC/030 Rev.05

Manufacturer's Name:	**MERIL HEALTHCARE PVT. LTD.**
Manufacturer's Address:	Ground & First Floor, Survey N0. 173/4 and First Floor, H1-H3, Meril Park, Survey No.135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat India
Product Name:	Latitud™ Hip Replacement system - Uncemented Femoral Stem
Product Details:	GMDN code: 33181 Product code/ Part No._____ Batch No.: _____ Mfg. Date : _____ Expiry Date: _____

We, the manufacturer, hereby declare under sole responsibility that the medical above devices, conform to the applicable provisions of EC Directive 93/42/EEC Annex II, as amended by 2007/47/EEC concerning medical devices. All supporting documentation is retained under premise of manufacturer.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2012, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 10993-1:2018, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN 1041:2008, ISO 14644-1:2015, ISO 14644-2:2015, ASTM F 1980:2016, MDD/93/42/EEC:2007, EN ISO 14630:2012, EN ISO 21534:2009, EN ISO 21535:2009, ASTM F136:2013, EN ISO 5832-3:2016, ISO 13779-2:2018.
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, excluding section 4
Device Classification:	Class III as per COMMISSION DIRECTIVE 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices.
Authorized Representative:	Obelis S.A., Bd. Général Wahis 53, 1030 Brussels, Belgium Tel: +32. 2. 732. 59. 54 Fax: +32. 2. 732. 60. 03 E-mail: mail@obelis.net
Quality System:	EN ISO 13485:2016/DIN EN ISO 13485:2016 (Certificate No.: Q5 105566 0001 Rev. 00 Valid till: 5 April 2023).
CE Certificate:	CE Certificate No.: 2195-MED-2106201 Valid till: 26 May 2024
Notifying Body:	Szutest Tatlisu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul Tel : + 90 216469 46 66
Notifying Body Number:	2195
Signature:	
Name:	Umesh Sharma
Designation:	GM-QA/RA
Date/Location:	**Date:27-03-2021** Location: Vapi, Gujarat, INDIA

Meril
Healthcare

DECLARATION OF CONFORMITY

Document No. MH/DOC/022 Rev.06

Manufacturer's Name:	**MERIL HEALTHCARE PVT. LTD.**
Manufacturer's Address:	Ground & First Floor, Survey N0. 173/4 and First Floor, H1-H3, Meril Park, Survey No.135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat India
Product Name:	Latitud™ Hip Replacement system - Bone Screw
Product Details:	GMDN code: 33181 Product code/ Part No._____ Batch No.: _____ Mfg. Date : _____ Expiry Date: _____

We, the manufacturer, hereby declare under sole responsibility that the medical above devices, conform to the applicable provisions of EC Directive 93/42/EEC Annex II, as amended by 2007/47/EEC concerning medical devices. All supporting documentation is retained under premise of manufacturer.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2019, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 10993-1:2018, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN 1041:2008, EN ISO 14644-1:2015, EN ISO 14644-2:2015, ASTM F 1980:2016, EN ISO 14630:2012, EN ISO 21534:2009, EN ISO 21535:2009, ASTM F136:2013, EN ISO 5832-3:2016, EN ISO/IEC 17050-1:2010, EN ISO/IEC 17050-2:2004, MDD/93/42/E 2.7/1; Rev.4/2016 MEDDEV 2.12/1; Rev.8/2013, MEDDEV 2.12/2; Rev.2/2012.
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, excluding section 4
Device Classification:	Class IIb as per Rule 8, Section 2.4, EC Directive 93/42/EEC
Authorized Representative:	Obelis S.A., Bd. Général Wahis 53, 1030 Brussels, Belgium Tel: +32. 2. 732. 59. 54 Fax: +32. 2. 732. 60. 03 E-mail: mail@obelis.net
Quality System:	EN ISO 13485:2016/DIN EN ISO 13485:2016 (Certificate No.: Q5 105566 0001 Rev. 00 Valid till: 5 April 2023).
CE Certificate:	CE Certificate No.: 2195-MED-2106201 Valid till: 26 May 2024
Notifying Body:	Szutest Tatlisu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul Tel : + 90 216469 46 66
Notifying Body Number:	2195
Signature:	
Name:	Umesh Sharma
Designation:	GM-QA/RA
Date/Location:	**Date:27-03-2021** Location: Vapi, Gujarat, INDIA

Meril
Healthcare

DECLARATION OF CONFORMITY

Document No. MH/DOC/026 Rev.05

Manufacturer's Name:	**MERIL HEALTHCARE PVT. LTD.**
Manufacturer's Address:	Ground & First Floor, Survey N0. 173/4 and First Floor, H1-H3, Meril Park, Survey No.135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat India
Product Name:	Latitud™ Hip Replacement system - Modular Femoral Head
Product Details:	GMDN code: 33181 Product code/ Part No._____ Batch No.: _____ Mfg. Date : _____ Expiry Date: _____

We, the manufacturer, hereby declare under sole responsibility that the medical above devices, conform to the applicable provisions of EC Directive 93/42/EEC Annex II, as amended by 2007/47/EEC concerning medical devices. All supporting documentation is retained under premise of manufacturer.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2019, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 10993-1:2018, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN 1041:2008, ASTM F 1980:2016, MDD/93/42.EEC:2007, EN ISO 14630:2012, EN ISO 21534:2009, EN ISO 21535:2009, ASTM F1537:2020, EN ISO 5832-12:2019, ASTM F1586:2013, ISO 5832-9:2019
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, excluding section 4
Device Classification:	Class III as per COMMISSION DIRECTIVE 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices.
Authorized Representative:	Obelis S.A., Bd. Général Wahis 53, 1030 Brussels, Belgium Tel: +32. 2. 732. 59. 54 Fax: +32. 2. 732. 60. 03 E-mail: mail@obelis.net
Quality System:	EN ISO 13485:2016/DIN EN ISO 13485:2016 (Certificate No.: Q5 105566 0001 Rev. 00 Valid till: 5 April 2023).
CE Certificate:	CE Certificate No.: 2195-MED-2106201 Valid till: 26 May 2024
Notifying Body:	Szutest Tatlisu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul Tel : + 90 216469 46 66
Notifying Body Number:	2195
Signature:	
Name:	Umesh Sharma
Designation:	GM-QA/RA
Date/Location:	**Date:27-03-2021** Location: Vapi, Gujarat, INDIA

Meril
Healthcare

DECLARATION OF CONFORMITY

Document No. MH/DOC/027 Rev.05

Manufacturer's Name:	**MERIL HEALTHCARE PVT. LTD.**
Manufacturer's Address:	Ground & First Floor, Survey N0. 173/4 and First Floor, H1-H3, Meril Park, Survey No.135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat India
Product Name:	Latitud™ Hip Replacement system - Modular Liner/ Elevated Wall Liner/ 10° Oblique Liner / +3mm 10° Oblique Liner
Product Details:	GMDN code: 33181 Product code/ Part No._____ Batch No.: _____ Mfg. Date : _____ Expiry Date: _____

We, the manufacturer, hereby declare under sole responsibility that the medical above devices, conform to the applicable provisions of EC Directive 93/42/EEC Annex II, as amended by 2007/47/EEC concerning medical devices. All supporting documentation is retained under premise of manufacturer.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2019, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 10993-1:2018, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN 1041:2008, ASTM F 1980:2016, MDD/93/42.EEC:2007, EN ISO 14630:2012, EN ISO 21534:2009, EN ISO 21535:2009, ASTM F648:2014, EN ISO 5834-1:2019.
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, excluding section 4
Device Classification:	Class III as per COMMISSION DIRECTIVE 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices.
Authorized Representative:	Obelis S.A., Bd. Général Wahis 53, 1030 Brussels, Belgium Tel: +32. 2. 732. 59. 54 Fax: +32. 2. 732. 60. 03 E-mail: mail@obelis.net
Quality System:	EN ISO 13485:2016/DIN EN ISO 13485:2016 (Certificate No.: Q5 105566 0001 Rev. 00 Valid till: 5 April 2023).
CE Certificate:	CE Certificate No.: 2195-MED-2106201 Valid till: 26 May 2024
Notifying Body:	Szutest Tatlisu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul Tel : + 90 216469 46 66
Notifying Body Number:	2195
Signature:	
Name:	Umesh Sharma
Designation:	GM-QA/RA
Date/Location:	**Date:27-03-2021** Location: Vapi, Gujarat, INDIA

Meril
Healthcare

DECLARATION OF CONFORMITY

Document No. MH/DOC/029 Rev.05

Manufacturer's Name:	**MERIL HEALTHCARE PVT. LTD.**
Manufacturer's Address:	Ground & First Floor, Survey N0. 173/4 and First Floor, H1-H3, Meril Park, Survey No.135/2/B & 174/2, Muktanand Marg, Chala, Vapi-396191, Gujarat India
Product Name:	Latitud™ Hip Replacement system - Modular Shell
Product Details:	GMDN code: 33181 Product code/ Part No._____ Batch No.: _____ Mfg. Date : _____ Expiry Date: _____

We, the manufacturer, hereby declare under sole responsibility that the medical above devices, conform to the applicable provisions of EC Directive 93/42/EEC Annex II, as amended by 2007/47/EEC concerning medical devices. All supporting documentation is retained under premise of manufacturer.

List of Standard Applied:	EN ISO 13485:2016, EN ISO 15223-1:2016, EN ISO 14971:2019, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 10993-1:2018, EN ISO 11607-1:2020, EN ISO 11607-2:2020, EN 1041:2008, EN ISO 14644-1:2015, EN ISO 14644-2:2015, ASTM F 1980:2016, MDD/93/42.EEC:2007, EN ISO 14630:2012, EN ISO 21534:2009, EN ISO 21535:2009, ASTM F136:2013, EN ISO 5832-3:2016, ASTM F1580:2018
Conformity Assessment Route:	Directive for medical devices 93/42/EEC, Annex II, excluding section 4
Device Classification:	Class III as per COMMISSION DIRECTIVE 2005/50/EC of 11 August 2005 on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices.
Authorized Representative:	Obelis S.A., Bd. Général Wahis 53, 1030 Brussels, Belgium Tel: +32. 2. 732. 59. 54 Fax: +32. 2. 732. 60. 03 E-mail: mail@obelis.net
Quality System:	EN ISO 13485:2016/DIN EN ISO 13485:2016 (Certificate No.: Q5 105566 0001 Rev. 00 Valid till: 5 April 2023).
CE Certificate:	CE Certificate No.: 2195-MED-2106201 Valid till: 26 May 2024
Notifying Body:	Szutest Tatlisu Mahallesi, Akif İnan Sk. No:1, 34774 Ümraniye/İstanbul Tel : + 90 216469 46 66
Notifying Body Number:	2195
Signature:	
Name:	Umesh Sharma
Designation:	GM-QA/RA
Date/Location:	**Date:27-03-2021** Location: Vapi, Gujarat, INDIA

SZUTEST

EC CERTIFICATE

According to Annex II of the Directive 93/42/EEC on Medical Devices

Full Quality Assurance System

Certificate Number: 2195-MED-2106201

Manufacturer: **Meril Healthcare PVT., LTD.**
Ground & First Floor, Survey No.173/4 and First Floor, H1-H3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396191 Gujarat, INDIA

Product(s):
1. Sterile and Non-Sterile Trauma System Implants
2. Sterile Hip Joint Implant System

Model(s):
1a. Non Sterile Bone Plates (ARTIS™/ARMAR™/DHUM™/KET™)
1b. Non Sterile Bone Screws (MBOSS™/FIXION™/DHUM™/KET™)
1c. Sterile and Non Sterile Intramedullary Nails (ACCURA™/CLAVO™/KET™)
2. Latitud ™ Hip Replacement System

Reference Report No: MM0849-P001-R01, MM0849-P001-R02, MM0849-P001-R03

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex II, Section 5 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements.

This EC certificate is valid till 2024-05-26.

Issue Date: 2021-03-03
Revision No.: 01 Rev.
Revision Date: 2021-03-19

Rukiye BALKAN
Deputy General Manager

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

EC DESIGN EXAMINATION CERTIFICATE

According to Annex II, Section 4 of the Directive 93/42/EEC on Medical Devices

Certificate Number: 2195-MED-2106201-D01

Manufacturer:	**Meril Healthcare PVT., LTD.** Ground & First Floor, Survey No.173/4 and First Floor, H1-H3, Meril Park, Survey No. 135/2/B & 174/2, Muktanand Marg, Chala, Vapi - 396191 Gujarat, INDIA
Product(s):	**Sterile Hip Joint Implant System**
Model(s):	Product specifications are stated on the following page(s).
Reference Report No:	MM0849-P001-R01, MM0849-P001-R03

Issued by Szutest, Notified Body 2195, this document certifies that the design documentation of the mentioned product complies with Annex II, Section 4 of the 93/42/EEC Medical Devices Directive.

The manufacturer is subject to EC surveillance in accordance with Annex II, Section 5 of 93/42/EEC Medical Devices Directive and unannounced audits.

This EC Design Examination certificate is valid till 2024-05-26.

Issue Date: 2021-03-19

Rukiye BALKAN
Deputy General Manager

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

Certificate Number: 2195-MED-2106201-D01

Product specifications:

Latitud ™ Hip Replacement System

1. Acetabular Cup System
- Modular Shell
- Modular Liner / Elevated Wall Liner / 10◦ Obligue Liner / +3mm 10◦ Obligue Liner
- Femoral Head / Biolox Delta™ Modular Femoral Head

Femoral Stem
- Uncemented Femoral Stem
- Cemented Femoral Stem
- Proximally Coated Uncemented Stem

Accessories
- Bone screw
- Modular Shell Apical Hole Cover
- Centralizer
- Cement Restrictor

2. Bipolar Cup System
- Bipolar Monoblock Shell
- Femoral Head

Femoral Stem
- Uncemented Femoral Stem
- Cemented Femoral Stem
- Proximally Coated Uncemented Stem

Accessories
- Centralizer
- Cement Restrictor

3. Acetabular Cemented Cup System
- Acetabular Cemented Cup
- Femoral Head / Biolox Delta™ Modular Femoral Head

Femoral Stem
- Uncemented Femoral Stem
- Cemented Femoral Stem
- Proximally Coated Uncemented Stem

Accessories
- Centralizer
- Cement Restrictor

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr