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 until 2024-05-26.

Digitally signed by Poiata Vitalie
Date: 2023.10.26 14:39:20 EEST
Reason: MoldSign Signature
Location: Moldova

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
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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

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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