

Healthcare

Manufacturer's Name: MERIL HEALTHCARE PVT. LTD.

Manufacturer's Address: 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

Product Details: GMDN code: 33181

Product code/ Part No.: MLAD-40/28 Batch No.: 08G0101A

Mfg. Date: 30/01/2020 Expiry Date: 29/01/2025

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

List of Standard Applied: EN ISO 13485, EN ISO 15223-1, EN ISO 14971, EN ISO 11137-1, EN ISO 11137-1, EN ISO 10993-1, EN ISO 11607-1, EN 1041, ASTM F 1980, MDD/93/42/EEC, EN ISO 21534, EN ISO 21535, ASTM F648, ISO 5834-2

Conformity Assessment Route: Directive for medical devices 93/42/EEC , Annex II, including 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 replacement 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: ISO 13485:2016/NS-EN-ISO 13485:2016 Certified
Certificate No.: 247064-2017-AQ-IND-NA-PS, Valid till: 18 Feb 2020

CE Certificate : CE Certificate no.: 245502-2017-CE-IND-NA-PS, Valid till: 10 May 2021

Notified Body : DNV GL PRESAFE AS,
Veritasveien 3, N-1363,
Hovik, Norway.
www.presafe.com

Notified Body Number : 2460

Signature:



Name: Nimesh B.

Designation: Sr. Manager QA

Date/Location: **Date:** 14/02/2020 **Location:** Vapi, Gujarat, INDIA

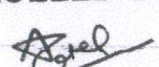
Brand Name : Latitud™ Hip Replacement System	
Product Name : Modular Liner	Size : 40/28
Manufactured By : Meril Healthcare Pvt. Ltd.	REF (Part No.): MLAD-40/28
Batch / Lot No. : 08G10101A	Batch Qty. (Nos.) : 47MS
Manufacturing Date : 30/01/2020	Expiry Date: 29/01/2025

Sr. No.	Test Parameter / Characteristics	Test Specification	Result
1	Material	Shall comply test as per ASTM-F648 GUR 1020 HXLPE-75kGy compression modular bar or sheet.	— HA —
		Shall comply test as per ASTM-F648 GUR 1020 HXLPE-90kGy compression modular bar or sheet.	Complies
2	Dimension & Visual Inspection	Dimensions shall comply with respective drawing & Surface Should be free from foreign particles, burrs, corners, dent marks. And also with proper Identification.	
3	Roughness Value	Ra Value shall be $\leq 0.8\mu\text{m}$	Complies
4	Sterility	No growth in the test media should be observed during incubation of 14 days.	Complies
5	Residual ETO content*	Ethylene oxide = $< 0.1\text{mg/device}$ Ethylene chlorohydrin = $< 0.4\text{mg/device}$	— HA —
6	Packaging	<u>Primary Packaging:</u> Components packed in inner and outer PETG trays with heat sealed Tyvek Lid.	Complies
		<u>Secondary Packaging:</u> The sterile components packed in laminated outer box, then labeled and shrink - wrapped.	
7	Labeling & printing	To be clear, neat, legible & indelible.	Complies

*Note: Residual ETO content Test is performed on every 10th Sterilization Cycle.

Remark: The above lot complies / does not comply with requirements.

Prepared By : <u>Bhaush</u>	Reviewed By : <u>[Signature]</u>	Approved By:
Name : <u>[Signature]</u>	Name : <u>Sudashan Patel</u>	Name
Sign & Date : <u>14/02/2020</u>	Sign & Date : <u>14/02/2020</u>	Sign & Date : <u>Patel 14/02/2020</u>

CONTROLLED COPY

 Sign.....