Meril

Healthcare

DECLARATION OF CONFORMITY

Document No. MH/DOC/027 Rev.01

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:	B. Patel
Name:	Nimesh B.
Designation:	Sr. Manager QA
Date/Location:	**Date:** 14/02/2020 **Location:** Vapi, Gujarat, INDIA

Digitally signed by
Date: 2023.10.06 1
Reason: MoldSign
Location: Moldova

Meril Healthcare

Batch Release Certificate

Document No. QA/FMT/042 Rev-03

Brand Name : Latitud™ Hip Replacement System	
Product Name : Modular Liner	Size : 40/28
Manufactured By : **Meril Healthcare Pvt. ltd.**	REF (Part No.): MLAD-40128
Batch / Lot No. : 08G10101A	Batch Qty. (Nos.) : 47 Nos
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.	— NA —
		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 ≤ 0.8µm	Complies
4	Sterility	No growth in the test media should be observed during incubation of 14 days.	Complies
5	Residual ETO content*	Ethylene oxide = < 0.1mg/device Ethylene chlorohydrin = < 0.4mg/device	— NA —
6	Packaging	Primary Packaging: Components packed in inner and outer PETG trays with heat sealed Tyvek Lid.	
		Secondary Packaging: The sterile components packed in laminated outer box, then labeled and shrink - wrapped.	Complies
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 : Bhavesh Name : Sign & Date : 14/02/2020	Reviewed By : Nitin Leel Name : Sign & Date : 14/02/2020	Approved By: Name Sudarshan Patel Sign & Date : Patel 14/02/2020

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Sign.....