EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
14278-2019-CE-IND-NA Rev.2.0	PRJC-585783-2018-PRC-IND	22 March 2024

This is to certify that the quality system of:

George Philips Medical Engineering Pvt. Ltd.

B-43, MIDC, Anand Nagar, Additional Ambernath, Ambernath (East) Thane District, 421506, Maharashtra INDIA

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

Sterile Disposable Diaphragm Domes, Spinal Manometer

Has been assessed with respect to:

THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING 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, 10 February 2020

NORWEGIAN ACCREDITATION

PROD 021

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Palani Damodharan

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

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	2019-03-22
1.0	Editorial Changes - addition of "-PS" in the certificate number	2019-04-04
2.0	**Scope extension**	**2020-02-10**

Products covered by this Certificate:

Product Description	Product Name	Class
Disposable Diaphragm Domes	Dome SENSEX 844	IIa
	Dome SENSEX 840	
	Dome SENSEX MDX	
	Dome SENSEX P23	
	Dome SENSEX 1295	
	Dome SENSEX MX960	
Spinal Manometer Set	**Spinal Manometer Set**	**IIa**
	Spinal Manometer Set With 3 Way Stopcock	

The complete list of devices is filed with the Notified Body

Site Name	Address
George Philips Medical Engineering Pvt. Ltd. (Thane)	B-43, MIDC, Anand Nagar, Ambernath (East), Thane District, 421506, Maharashtra, INDIA

EU Representative

MEDIKOKIM TIBBI KIMYEVI. SAN. TIC.LTD.STI, Demirciler Sanayi Sitesi, B/7 Blok No: 157, Basaksehir34306, Istanbul, Turkey

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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