EC DECLARATION OF CONFORMITY

EUROLATEX SDN. BHD

Factory Address:

Plot 33, Kuala Ketil Industrial Estate,

09300 Kuala Ketil,

Kedah,

MALAYSIA

declares that the medical device described hereafter

Latex Probe covers

have been classified as **Class IIa** device in accordance with Rule 5 of Annex IX and are in conformity with the essential requirement and provision of Medical Device Directive 93/42/EEC as amended by Directive 2007/47/EC and is subject to the procedure set out in Annex II of Directive 93/42/EEC as amended by Directive 2007/47/EC under the supervision of Notified Body BSI (CE 2797).

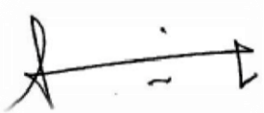
EU Representative:

CIRIANO GLOBAL S.L.

C/Blancas 4-6, 1 B

50001 Zaragoza, Spain

Date: 07/10/2019



Mr. Subramaniam

Managing Director

EUROLATEX SDN. BHD