LUMINOUS GLOBAL®

Declaration of Conformity

(according to Regulation (EU) 2017/745 on medical devices, annex IV dated May 2017)

Manufacturer:

Luminous Global LLC

US-MF-000035244

16192 Coastal Hwy, DL 19958, USA

European Authorized Representative:

be-on-market GmbH

DE-AR-000006148

Lilienstraße 33, 91244 Reichenschwand, Germany

declares under its sole responsibility that the products

08600103076_PLB_Q5

Luminous

And it's variant under the same Basic UDI-DI:

Luminous Pro-Series

The device (PLB, PLB Pro-Series) is used as an adjunctive to other clinical diagnostic screening procedures like mammography, clinical breast examination, self-breast examination for the early detection of breast abnormalities or diseases or cancer or other conditions. The use of the device is not intended to replace the mammography, clinical breast examination or self-breast examination for breast screening. It is not a sole diagnostic screening device. It is not a diagnostic device. It is intended for adjunctive diagnostic screening.

Luminous UDI-DI: 0860010307601

Luminous Pro-Series UDI-DI: 00860010307618

to which this declaration relates is in conformity with the following regulation:

Evaluation procedure according to Regulation (EU) 2017/745 on medical devices, annex IV, IX and related laws

Classification according to Regulation (EU) 2017/745 on medical devices, annex VIII:

active medical device class I according to classification rule Classification rule 10 (first subrule) and 13

This product has been CE-labelled due to the fulfilment of the general safety and performance requirements according to Regulation (EU) 2017/745 on medical devices, annex I.

CE