



# Certificate of Compliance

This is to certify that the technical documentation for the product:

**IBreastExam Medical Device**  
(Product Details as per Annexure 1)

Manufactured by:

**UE LifeSciences (India) Pvt. Ltd.**

302, Trimbak Niwas, Relcon House, M.G. Road, Ville Parle (East), Mumbai - 400057  
(Maharashtra), India.

Complies with the applicable requirements of **Medical Devices Directive 93/42/EEC**  
**Class I Medical Device**

The technical documentation / inspection / test results comply with the requirements of **Medical Devices Directive (MDD)**, hence manufacturer's declaration of conformity according to above directive is accepted. **UE LifeSciences (India) Pvt. Ltd.** can place the CE marking as per laid down regulations on the Products listed in Annexure.

**Certificaat Nummer / Certificate No. : CE-BV-2212-5889**

Date of This Certificate Issue : 22/12/2022  
Vervaldatum / Date of Expiry : 21/12/2025  
Ist Annual surveillance audit due on : 21/10/2023  
IInd Annual surveillance audit due on : 21/10/2024

**Director (Certification)**

**Royal Stancert B.V.**

**Feitelijke Beoordelingen - Wereldwijde Beoordelingen**

**Regd. Office** - Joop Geesinkweg 701, 1114 AB Amsterdam, The Netherlands.  
(KvK-Nummer 71431802 / RSIN 858713159 - Rechtsvorm - Besloten Vennootschap).

This certificate remains the property of **Royal Stancert B.V.** and must be returned whenever demanded. The validity of this certificate can be verified at <http://www.royalstancert.org>. **Royal Stancert B.V.** is an independent system, product and personal assessment body accredited by Global Euro Accreditation Centre, Georgia. (GCIN - 654). Email: [info@royalstancert.org](mailto:info@royalstancert.org)



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PAC-GEAC-1506-299



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**Annexure 1 to CE Conformity Certificate No. CE-BV-2212-5889**  
**Products covered by this certificate:**

Product	
iBreastExam	Device is intended to produce a surface pressure map of the breast as an aid in detecting and documenting breast lesions identified in the breast. Device is intended for use by a qualified healthcare professional trained in its use. The patient population includes adults.

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