

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

**No.****CE 740805****Issued To:**

**Hologic, Inc.  
36 Apple Ridge Road  
Danbury  
Connecticut  
06810  
USA**

In respect of:

**Design, Manufacture and final inspection of X-Ray Diagnostic Devices, Breast Biopsy Systems, PACS Workstations, Bone Densitometers and Radiological Image Analyses Systems**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex II excluding section 4. The quality assurance system meets the requirements of the directive. For the placing on the market of class III products an Annex II section 4 certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2021-05-06**

Date: **2021-05-06**

Expiry Date: **2024-05-26**

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Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.

This certificate was issued electronically and is bound by the conditions of the contract.

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## Supplementary Information to CE 740805

Issued To:

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Device code	Device name	Intended purpose per IFU
<b>Class IIb</b>		
MD 1201 GMDN 37672	Mammographic X-ray systems	Intended to be used for screening and diagnosis of breast cancer
MD 1201 GMDN 36190	Mammographic stereotactic biopsy system	Intended for localizing lesions in the breast in two and/or three dimensions, and then providing guidance for interventional purposes (such as biopsy, pre-surgical localization or treatment devices) for lesions determined to be suspicious through prior mammographic examination
MD 1201 GMDN 37661	Bone absorptiometric x-ray system, dual-energy	Intended to be used for bone density measurements, body composition and other calculations
MD 1201 GMDN 37646	Fluoroscopic x-ray system, digital	Designed to provide the physicians with general fluoroscopic visualization of a patient, including, but not limited to surgical, orthopedic, and podiatry use, critical and emergency care procedures, and light anatomy imaging situations.
<b>Class IIa</b>		
MD 1111	PACS Workstations	---
MD 1111	Radiological Image Analyses Systems	---

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Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780

BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.

A member of BSI Group of Companies.

# EC Certificate - Full Quality Assurance System

Directive 93/42/EEC on Medical Devices, Annex II excluding Section 4

## List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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 Date: **2021-05-06**  
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**36 Apple Ridge Road**  
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**06810**  
**USA**

Subcontractor:	Service(s) supplied
Cogmedix, Inc. 127 Hartwell Street West Boylston, MA 01583 USA	Crucial Supplier
Flextronics Manufacturing Aguascalientes, S.A. de C.V. Boulevard a zacatecas Km. 9.5 Jesús María Aguascalientes 20900 Mexico	Manufacture
Hologic BV Da Vincilaan 5 1930 Zaventem Belgium	EU Representative
Hologic, Inc. 37 Apple Ridge Road, Danbury CT 06810 USA	Manufacture

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**USA**

Subcontractor:	Service(s) supplied
Hologic, Inc. 445 Simarano Drive Marlborough Massachusetts 01752 USA	Installation
Hologic, Inc. 250 Campus Drive Marlborough MA 01752 USA	Design
Hologic, Inc. 2520 Mission College Blvd. Suite 202 Santa Clara CA 95054 USA	Design

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**USA**

Subcontractor:	Service(s) supplied
Hologic, Inc. Direct Radiography Division Glasgow Business Community 600 Technology Drive Newark, Delaware 19702 USA	<b>Design</b> <b>Manufacture</b>
MeVis BreastCare GmbH & Co. KG Caroline-Herschel-StraBe 1 28359 Bremen Germany	<b>Design</b>
Protek Medical Products, Inc. 4125 Westcor Court Coralville, Iowa 52241 USA	<b>Design</b> <b>Manufacture</b>

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Subcontractor:	Service(s) supplied
Topex Inc. 10 Precision Road Danbury CT 06810 USA	Design Manufacture
Varex Imaging Corporation 1678 South Pioneer Road Salt Lake City Utah 84104 USA	Design Manufacture

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# EC Certificate - Full Quality Assurance System

## Certificate History

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Date	Reference Number	Action
Current	3335577	Issued – Voluntary change of Notified Body (Transfer from <b>TÜV NORD CERT GmbH</b> 0044 – Certificate No. 44 232 117808)

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