

EC Certificate - Full Quality Assurance System

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

No. CE 669061
Issued To: **Varex Imaging Corporation**
121 Metropolitan Drive
Liverpool
New York
13088
USA

In respect of:

Design, Development and Manufacture of digital X-ray imaging systems and software.

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):



Albert Roossien, Regulatory Lead

First Issued: **2017-03-28**

Date: **2019-03-25**

Expiry Date: **2023-06-17**

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Page 1 of 1

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.

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.

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List of Significant Subcontractors

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

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Subcontractor:

Service(s) supplied

Arazy Group GmbH
Am Kalkofen 8
Wöllstadt
61206
Germany

EU Representative

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EC Certificate - Full Quality Assurance System Certificate History

Certificate No: **CE 669061**
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Date	Reference Number	Action
28 March 2017	8648156	Initial Application. Devices previously covered by EC Certificate CE 589083.
18 June 2018	8888341	EC Certificate Renewal; Change of EU Authorized Representative from MeVis Medical Solutions AG to Arazy Group GmbH.
Current	8939261	Traceable to NB 0086.

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Page 1 of 1

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