

EC Certificate - Full Quality Assurance System

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

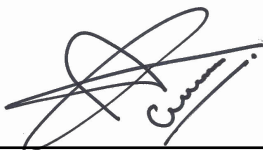
No. **CE 697335**
Issued To: **Varex Imaging Deutschland AG**
In der Rehbach 22
Walluf
65396
Germany

In respect of:

The Design and Manufacture of Panels and Detectors for X-Ray Imaging Applications

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: **2018-12-11**

Date: **2019-03-25**

Expiry Date: **2020-04-08**

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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.

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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Supplementary Information to CE 697335

Issued To:

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Number	Device Name	Intended purpose per IFU
Class IIa		
MD 1201 MDS 7010	XRpad, XRpad2	N/A – for Class IIa devices

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List of Significant Subcontractors

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

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Walluf
65396
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Subcontractor:

Service(s) supplied

Varex Imaging
dba PerkinElmer Medical Imaging, LLC
2175 Mission College Boulevard
Santa Clara
California
95054
USA

Design
Manufacture

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Certificate History

Certificate No: **CE 697335**
 Date: **2019-03-25**
 Issued To: **Varex Imaging Deutschland AG**
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Date	Reference Number	Action
11 December 2019	9626605	First issue. Transfer for another Notified Body.
Current	8939261	Traceable to NB 0086.

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