

EC Certificate Full Quality Assurance System: BE11/23574288

The management system of

**Varex Imaging Group Nederland B.V.**  
also doing business as Claymount and/or Varex  
Imaging

Anholtseweg 44, 7091 HB Dinxperlo, The Netherlands

has been assessed and certified as meeting the requirements of

**Directive 93/42/EEC**  
on medical devices, Annex II (excluding Section 4)

For the following products

**The scope of registration appears on page 2 of this certificate.**

This certificate is valid from 01 January 2019 until 30 January 2022  
and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 31 December 2019  
Issue 8. Certified since 01 February 2011

Certification is based on reports numbered BE/AND 10/1146.QMD

This is a multi-site certification.  
Additional site details are listed on subsequent pages.

Authorised by



**SGS United Kingdom Ltd, Notified Body 0120**

SGS United Kingdom Ltd  
202B Worle Parkway, Weston-super-Mare, BS22 6WA UK  
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

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**Imaging**

**Directive 93/42/EEC**

on medical devices, Annex II (excluding section 4)

Issue 8

Detailed scope

- Solid state measuring chambers for automatic exposure control of X-ray diagnostic systems, including an electronic pre-amplifier
- Ionization chambers for X-ray diagnostic systems
- Collimator for X-ray diagnostic systems, including Optica 20
- Sensitive Compression Mammography Paddle

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market

Additional facilities

**Varex Imaging Nederland B.V. also doing business as Claymount and/or Varex**  
**Imaging,**  
**Anholtseweg 44, 7091 HB Dinxperlo, The Netherlands**

**Varex Imaging Americas Corp. also doing business as Clymount and/or Varex**  
**Imaging,**  
**3835 Carnation Street, Franklin Park, Illinois, 60131, United States**

**Varex Imaging Philippines Inc. also doing business as Claymount and/or Varex**  
**Imaging,**  
**Bldg. 9, 10 & 11 Harvard Avenue, EZP Business Park,**  
**Calamba Premiere International Park-SEZ, Batino,**  
**Calamba City, 4027 Laguna, Philippines**

