

EC Certificate Full Quality Assurance System: Certificate BE19/819943480

The management system of

**Varex Imaging Group Nederland B.V.**  
**also doing business**  
**as Claymout 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 12/08/2019 until 30/01/2022  
and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 01/02/2011

And first certified by SGS Belgium on 12/08/2019

Re certification audit due before 31/12/2019

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



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Certification Manager

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

**Directive 93/42/EEC**

on medical devices, Annex II (excluding Section 4)

Issue 1

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 Claymount 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**

