

EC Certificate Full Quality Assurance System: Certificate BE19/819943480

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 12/08/2019 until 30/01/2022 and remains valid subject to satisfactory surveillance audits.

Issue 1. Certified since 01/02/2011

And first certificated 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

Pieter Weterings Certification Manage

SGS Belgium NV, Notified Body 1639

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LPMD5007 - Certificate CE1639 Annex II-4_EN rev. 02

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Certificate BE19/819943480 continued

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

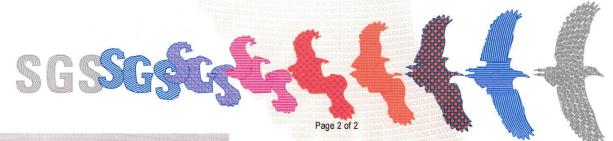
Varex Imaging Americas Corp. also doing business as Claymount and/or Varex Imaging,

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





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