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

Fabriekstraat 41 7005 AP Doetinchem, 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 24 November 2020 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.

Issue 6. Certified since 01 February 2011 and first certified by SGS Belgium NV since 12 August 2019.

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

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

Authorised by

SGS Belgium NV, Notified Body 1639

SGS House Noorderlaan 87 2030 Antwerp Belgium t +32 (0)3 545-48-48 f +32 (0)3 545-48-49 www.sgs.com

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## **Directive 93/42/EEC**

on medical devices, Annex II (excluding Section 4)

Issue 6

Detailed scope

Solid state measuring chambers for automatic exposure control of X-ray diagnostic systems, including an electronic pre-amplifier lonization chambers for X-ray diagnostic systems Manual and motorized controlled Collimators for X-ray diagnostic systems

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

Fabriekstraat 41, 7005 AP Doetinchem, 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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