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

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 6

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
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

Supplementary information to AR120 809704

Non-significant changes approved after the 26th May 2021 as per the Transitional Provisions of MDR Article 120.3

Issued to:

Varex Imaging Group Nederland B.V.
also doing business as Claymount and/or Varex Imaging
Fabriekstraat 41
Doetinchem
7005 AP
The Netherlands

Date: 23 May 2024

Changes Approved:

Date	Reference Number	Action
23 May 2024	30181641	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Optica 10 series/collimator, Optica 20 series/collimator, Optica 30/40/50 series/collimator, SolidStateMC series/ dosimeter, AmpMC series/amplifier (Used with the SolidStateMC series), Ionization Chamber series/ dosimeter. Original NB Certificate Number: BE19_819943480

Inspiring trust for a more resilient world.

23rd May 2024

Varex Imaging Group Nederland B.V.
also doing business as Claymount and/or Varex Imaging
Fabriekstraat 41
Doetinchem
7005 AP
The Netherlands

To whom it may concern,

The transitional provisions specified in MDR Article 120(3) (as amended by (EU) 2023/607) prohibit Notified Bodies from issuing new certificates or amending, modifying, supplementing any existing MDD/AIMDD certificates from 26th May 2021.

This letter is to confirm that BSI has reviewed and approved the change(s) detailed in the table below. These changes do not represent a significant change in design or intended purpose under MDR Article 120(3) (as amended by (EU) 2023/607) and as per the guidance provided in MDCG 2020-3.

The related MDD certificate specified below remains valid until the expiry date stated on the certificate or until the end of the transition period as specified in Article 120(3c) of MDR (as amended by (EU) 2023/607), subject to the manufacturer's continued compliance to the other conditions provided in Article 120(3c) of MDR (as amended by (EU) 2023/607).

Original Certificate Number	**BSI Reference Number**	**Directive and Annex**	**Reference Number**	**Changes approved**
BE19_819943480	AR120 809704	93/42/EEC Annex II excluding Section 4	30181641	Transfer of appropriate surveillance to BSI per Regulation (EU) 2023/607 of Optica 10 series/collimator, Optica 20 series/collimator, Optica 30/40/50 series/collimator, SolidStateMC series/ dosimeter, AmpMC series/amplifier (Used with the SolidStateMC series), Ionization Chamber series/ dosimeter. Original NB Certificate Number: BE19_819943480

Should you have any queries concerning your certification, or if we can be of further assistance to you, please contact your BSI Scheme Manager.

Yours sincerely,

Graeme Tunbridge
Senior Vice President, Medical Devices

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