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

EC Declaration of Conformity

Varex Imaging Group Nederland B.V.
Fabriekstraat 41
7005 AP Doetinchem
The Netherlands

netherlands.cnc@vareximaging.com
www.vareximaging.com
Chamber of Commerce - Arnhem
No.:09066495

We, the

Manufacturer:	Varex Imaging Group Nederland B.V. Fabriekstraat 41 7005 AP Doetinchem The Netherlands
Single registration number:	N/A

hereby declare that the products

Product name:	Ionization Chamber for X-Ray diagnostic systems
Product intended use:	A Varex Ionization Chamber is a medical device that is placed between the patient and an x-ray image receptor to assist the Automatic Exposure Control (AEC) in delivering the proper x-ray dose in medical radiography.
Model numbers:	As listed in Table 1
Device Identifiers:	As listed in Table 1
GMDN-code:	38326(Ionization chamber radiation measuring probe)

are in conformity the European Medical Directive and fulfils the Essential Requirements thereof

Council Directive 93/42/EEC (MDD)
Concerning medical devices (revision 2007-09-27)
Subject to the procedure set out in Annex II (excluding section 4)
Class IIb, according to Annex VIII.

and are in conformity with the European directives/regulations

Council Directive 2014/30/EU (EMC)
on the harmonisation of the laws of the Member States relating to electromagnetic compatibility.
Council Directive 2011/65/EU (RoHS)
on the restriction of the use of certain hazardous substances in electrical and electronic equipment.
Regulation 1907/2006 (REACH)
concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals

Notified Body: For MDD only, SGS Belgium (CE_{1639})

This declaration is issued under the sole responsibility of Varex Imaging Group Nederland B.V. and based upon Quality Assurance certificate N°. BE19/819943480, issued by Notified Body, SGS Belgium and valid from 2019, August 12.

Name: Position: Address:	Mark Megens Technical Director Varex Imaging Group Nederland B.V. Fabriekstraat 41 7005 AP Doetinchem The Netherlands	Signature:	2020-04-03 Date: <yyyy-mm-dd>
Name: Position: Address:	Eva Garza QA/RA Manager Varex Imaging Americas Corp. 3835 Carnation Street Franklin Park, Illinois 60131 U.S.A.	Signature:	2020-04-02 Date: <yyyy-mm-dd>

Table 1

Model number	Device Identifier (part of UDI)	Tradename
Ionization chambers beginning with either ICX or INX with suffix B	NA	NA

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Varex Imaging Corporation
1678 South Pioneer Road
Salt Lake City
Utah
84104
USA

Holds Certificate No: **FM 77566**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The design, development, manufacture, distribution and full refurbishment of medical X-ray generating tube products and X-ray imagers and imaging components.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2003-10-29
Latest Revision Date: 2021-04-14

Effective Date: 2021-06-06
Expiry Date: 2024-06-05

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