

EC Declaration of Conformity

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

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 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 (CE₁₆₃₉)

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: Mark Megens Position: Technical Director Address: Varex Imaging Group Nederland B.V. Fabriekstraat 41 7005 AP Doetinchem The Netherlands	 Signature:	2020-04-03 Date: <yyyy-mm-dd>
Name: Eva Garza Position: QA/RA Manager Address: 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