

EC Declaration of Conformity

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

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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: SolidStateMC series (Solid State Measuring Chambers)
Product intended use: The Solid State Measuring Chambers are intended to measure the dose rate of X-rays by conversion of X-ray photon energy to an electrical current that is proportional to the X-ray dose rate
Model numbers: As listed in Table 1
Device Identifiers: As listed in Table 1
GMDN-code: 38336

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:
Position: QA/RA Manager
Date: 2020-04-10
Address: Varex Imaging Group Nederland B.V.
Fabriekstraat 41
7005 AP Doetinchem
The Netherlands

Signature:



Table 1

Model number	Device Identifier (part of UDI)	Tradename
SolidStateMC 501	8718755000993	Claymount / Varex Imaging
SolidStateMC 502	8718755001006	Claymount / Varex Imaging
SolidStateMC 506	8718755001013	Claymount / Varex Imaging
SolidStateMC 508	8718755001037	Claymount / Varex Imaging
SolidStateMC 510	8718755001044	Claymount / Varex Imaging
SolidStateMC 521	8718755001051	Claymount / Varex Imaging
SolidStateMC 601	8718755001068	Claymount / Varex Imaging
SolidStateMC 605	8718755001075	Claymount / Varex Imaging
SolidStateMC 609	8718755001082	Claymount / Varex Imaging
SolidStateMC 610	8718755001099	Claymount / Varex Imaging
SolidStateMC 613	8718755001105	Claymount / Varex Imaging
SolidStateMC 614	8718755001112	Claymount / Varex Imaging
SolidStateMC 616	8718755001129	Claymount / Varex Imaging
SolidStateMC 617	8718755001136	Claymount / Varex Imaging
SolidStateMC 619	8718755001143	Claymount / Varex Imaging
SolidStateMC 621	8718755001150	Claymount / Varex Imaging
SolidStateMC 625	8718755002034	Claymount / Varex Imaging