

# EC Declaration of Conformity

Varex Imaging Group Nederland B.V.  
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The Netherlands

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Chamber of Commerce – Arnhem  
No.:09066495

We hereby declare that the products indicated in Annex I are in conformity with the indicated directives.

Manufacturer: Varex Imaging Group Nederland B.V.  
Anholtseweg 44  
7091 HB Dinxperlo  
The Netherlands

Single registration number: N/A

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 Annex I**


Device Identifiers: **As listed in Annex I**

GMDN-code: 38336

Directive(s): 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 IX, rule 10  
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<sub>1639</sub>)

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

Name: Kees Eilander	Signature:
Position: QA/RA Manager	
Date: 2019-12-18	
Address: Varex Imaging Group Nederland B.V. Anholtseweg 44 7091 HB Dinxperlo The Netherlands	

## Annex I

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