

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: AmpMC (Electronic Preamplifier)
Product intended use: The AmpMC is intended to convert an electrical current from a Solid State Measuring Chamber to a voltage ramp or voltage level that can be interpreted by the Automatic Exposure Control interface of a High Voltage Generator.
Model numbers: As listed in Table 1
Device Identifiers: As listed in Table 1
GMDN-code: 38337

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

Table 1

Model number	Device Identifier (part of UDI)	Tradename
AmpMC 1001	8718755000924	Claymount / Varex Imaging
AmpMC 1002	8718755000931	Claymount / Varex Imaging
AmpMC 1006	8718755000948	Claymount / Varex Imaging
AmpMC 1006, Config 1	8718755000955	Claymount / Varex Imaging
AmpMC 1007	8718755000962	Claymount / Varex Imaging
AmpMC 1008	8718755000979	Claymount / Varex Imaging
AmpMC 1012	8718755000986	Claymount / Varex Imaging