

# EC Declaration of Conformity

Varex Imaging Group Nederland B.V.  
Anholtseweg 44  
7091 HB Dinxperlo  
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: **Harmony3 series**

Product intended use: **The device is intended to be used in medical diagnostic applications with restrictions to human diagnostics as an accessory of an X-ray system in a professional healthcare facility environment and is intended to be holding image receptor.**

Model numbers: **As listed in Annex I**

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

GMDN-code: 14473 (X-ray film cassetholder)

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 I, according to Annex IX, rule 12  
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

This declaration is issued under the sole responsibility of Varex Imaging Group Nederland B.V.

Name: Kees Eilander  
Position: QA/RA Manager  
Date: 2109-04-03  
Address: Varex Imaging Group Nederland B.V.  
Anholtseweg 44  
7091 HB Dinxperlo  
The Netherlands

Signature:



## Annex I

Model number	Device Identifier (part of UDI)	Tradename
19386-01	8718755001457	Claymount / Varex Imaging
19386-02	8718755001921	Claymount / Varex Imaging
19386-03	8718755001464	Claymount / Varex Imaging
19387-01	8718755001471	Claymount / Varex Imaging
19387-02	8718755001488	Claymount / Varex Imaging
19387-03	8718755001495	Claymount / Varex Imaging
19387-04	8718755001501	Claymount / Varex Imaging
19387-05	8718755001518	Claymount / Varex Imaging
19387-06	8718755001525	Claymount / Varex Imaging
19387-07	8718755001532	Claymount / Varex Imaging
19387-08	8718755001549	Claymount / Varex Imaging
19388-01	8718755001556	Claymount / Varex Imaging
19388-02	8718755001563	Claymount / Varex Imaging
19388-03	8718755001662	Claymount / Varex Imaging
19388-04	8718755001914	Claymount / Varex Imaging
19407-01	8718755001570	Claymount / Varex Imaging
19407-02	8718755001587	Claymount / Varex Imaging
19407-03	8718755001594	Claymount / Varex Imaging
19407-04	8718755001600	Claymount / Varex Imaging
19407-05	8718755001617	Claymount / Varex Imaging
19407-06	8718755001624	Claymount / Varex Imaging
19407-07	8718755001631	Claymount / Varex Imaging
19407-08	8718755001648	Claymount / Varex Imaging
19407-09	8718755001655	Claymount / Varex Imaging
19408-01	8718755001679	Claymount / Varex Imaging
19408-02	8718755001686	Claymount / Varex Imaging
19408-03	8718755001693	Claymount / Varex Imaging
19408-04	8718755001709	Claymount / Varex Imaging
19408-05	8718755001716	Claymount / Varex Imaging
19408-06	8718755001723	Claymount / Varex Imaging
19408-07	8718755001730	Claymount / Varex Imaging
19408-08	8718755001747	Claymount / Varex Imaging
19408-09	8718755001754	Claymount / Varex Imaging
19408-10	8718755001761	Claymount / Varex Imaging
19409-01	8718755001778	Claymount / Varex Imaging
19409-02	8718755001785	Claymount / Varex Imaging
19409-03	8718755001792	Claymount / Varex Imaging
19409-04	8718755001808	Claymount / Varex Imaging

19409-05	8718755001815	Claymount / Varex Imaging
19409-06	8718755001822	Claymount / Varex Imaging
19409-07	8718755001839	Claymount / Varex Imaging
19409-08	8718755001846	Claymount / Varex Imaging
19409-09	8718755001853	Claymount / Varex Imaging
19409-10	8718755001860	Claymount / Varex Imaging
19410-01	8718755001877	Claymount / Varex Imaging
20947-00	8718755001884	Claymount / Varex Imaging
20948-00	8718755001891	Claymount / Varex Imaging
20949-00	8718755001907	Claymount / Varex Imaging
19407-10	8718755001976	Claymount / Varex Imaging