

KONICA MINOLTA

EU DECLARATION OF CONFORMITY

Manufacturer

Name KONICA MINOLTA, INC.
Address 1 Sakura-machi, Hino-shi, Tokyo, 191-8511, Japan

declares, sole responsibility, that the following product

GMDN term: General ultrasound imaging system, line-powered
GMDN code: 40761
Generic Device Group: Diagnostic Ultrasound Systems
Type: Diagnostic Ultrasound System
Model: ULTRASOUND SYSTEM SONIMAGE HSI
Classification: Class IIa, Rule 10, 1st sub-clause 1st indent, 93/42/EEC
Including components shown in other page(s) of this declaration.

referred to in this declaration conforms with the following EU law(s) :

DIRECTIVE 93/42/EEC, confirmed by the procedure of its Annex II, and
Directive 2011/65/EU

and conforms with the following standard(s):

EN 60601-1:2006+A1:2013 (NOTE 2) or EN 60601-1:2006+AC:2010 (NOTE 1),
EN 60601-1-2:2007+AC:2010, EN 62304:2006+AC:2008, EN 62366:2008,
EN 60601-1-6:2010, EN 60601-2-37:2008, EN ISO 10993-1:2009+AC:2010,
EN ISO 10993-5:2009, EN ISO 10993-10:2013, EN ISO 10993-12:2012,
EN ISO 14971:2012, EN ISO 13485:2012+AC:2012 and EN 1041:2008 for DIRECTIVE
93/42/EEC,
EN 50581:2012 for Directive 2011/65/EU

and that this declaration is valid upon approval for release of each product.
The manufacturer will keep on file for review the technical documentation.

EU Representative

Name Konica Minolta Business Solutions Europe GmbH
Address Hoogoorddreef 9, 1101 BA Amsterdam, The Netherlands

Notified Body responsible only for implementation of the Directive 93/42/EEC

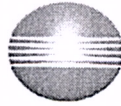
Name TÜV Rheinland LGA Products GmbH
Address Tillystrasse 2, 90431 Nürnberg, Germany

Signed for and on behalf of manufacturer:

Tokyo Japan, 2017-10-01
(Place and date of issue)
YASUSHI YAMANAKA
General Manager,
Quality Assurance Operations
Healthcare Business Unit
Healthcare Business Headquarters
(Name, function)

(Signature of equivalent authorized by the manufacturer)

CE 0197



KONICA MINOLTA

Components and their Serial Numbers

Name of Component	Serial Numbers for the Component		NOTE
	from	to	
ULTRASOUND SYSTEM SONIMAGE HS1	A8AR-00073	A8AR-99999	NOTE 1
	A8WA-00180	A8WA-99999	NOTE 1
	A9RP-00092	A9RP-99999	NOTE 2
	A9RR-00029	A9RR-99999	NOTE 2
	AAEU-00056	AAEU-99999	NOTE 2
ULTRASOUND SYSTEM SONIMAGE HS1 (SONIMAGE HS1 PLUS)	A8FW-00026	A8FW-99999	NOTE 1, 4
SONIMAGE HS1 Pole Cart	A7AR-00108	A7AR-99999	
SONIMAGE HS1 Power Extension Unit	A7AW-00109	A7AW-99999	
SONIMAGE HS1 Foot Switch (Dual)	A7C0-00016	A7C0-99999	
SONIMAGE HS1 Foot Switch (Triple)	A7C1-00001	A7C1-99999	
SONIMAGE HS1 Keyboard Kit	A7CH-00001	A7CH-99999	
SONIMAGE HS1 CW Kit	A7CW-00001	A7CW-99999	
SONIMAGE HS1 ECG Unit	A7AY-00001	A7AY-99999	
SONIMAGE HS1 VESA Attachment	A7CK-00001	A7CK-99999	
SONIMAGE HS1 Three-Port Probe Unit	A7AX-00001	A7AX-99999	
SONIMAGE HS1 Cable Hanger	A7C2-00001	A7C2-99999	
SONIMAGE HS1 Reference Signal Unit	A9KW-00001	A9KW-99999	
SONIMAGE HS1 V1.31 Operation Manual kit	A9RU-00061	A9RU-99999	

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Components without their Serial Numbers

Name of Component	Serial Numbers for the Component		NOTE
	from	to	
Clear Ball	Not applied	Not applied	
SONIMAGE HS1 Acoustic Standoff	Not applied	Not applied	NOTE 3
SONIMAGE HS1 V1.2 Operation Manual kit	Not applied	Not applied	

NOTE 1: ULTRASOUND SYSTEM SONIMAGE HS1 including ULTRASOUND SYSTEM SONIMAGE HS1 of which Serial Number starts A8AR, A8AW or A8FW as a main component complies with EN 60601-1:2006+AC2010.

NOTE 2: ULTRASOUND SYSTEM SONIMAGE HS1 including ULTRASOUND SYSTEM SONIMAGE HS1 of which Serial Number starts A9RP, A9RR or AAEU as a main component complies with EN 60601-1:2006+A1:2013.

NOTE 3: This component is controlled as per lot. The lot to which the Declaration is applied is from 1st lot.

NOTE 4: This component is named 'SONIMAGE HS1 PLUS' for CFDA.

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