DECLARATION OF CONFORMITY

Manufactuer: Address:	Hitachi Aloka Medical, Ltd. 6-22-1 Mure, Mitaka-shi, Tokyo 181-8622 Japan
selected conformity assessment procedure:	Annex Ⅱ excluding (4)
European Representative: Address:	Hitachi Medical Ultrasound Logistics, Zweigniederlassung der Hitachi Medical Systems Europe Holding AG Carl-Zeiss-Strasse 5 D-72555 Metzingen Germany
Product:	*Puncture Electronic Convex Probe*
Model Code::	*UST-9113P-3.5*
Classification (MDD, Annex IX):	Ⅱa

We herewith declare that the above mentioned products including all its accessories meet the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive : Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices Directive (93/42/EEC as amended by 2007/47/EC; MDD)

Standards : Harmonized Standards (published in the Office Journal of the European Communities) applicable to this product are :

EN 60601-1(2006)/AC(2010), EN 60601-1-2(2007)/AC(2010)
EN 60601-2-37(2008), EN 62366(2008), EN 60601-1-6(2010)
EN 980(2008), EN 1041(2008)

Other Standards :

EN ISO 14971(2009), EN ISO 10993-1(2009)/AC(2010)
IEC 62079(2001), ISO 7010(2003)/A1(2006)
ISO 3864-2(2004)

Notified body : TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
Address: Ridlerstraße 65, 80339 München, Germany

Start of CE marking: SN : *After 20143615*

Place : ***Hitachi Aloka Medical,Ltd. Tokyo Works***

Date: ***31. May. 2012***

Signature: MASAAKI HIRAKAWA

Name of issuer : Masaaki Hirakawa
Position : General Manager of Quality Assurance Department