

# DECLARATION OF CONFORMITY

Manufacturer: Hitachi Aloka Medical, Ltd.  
Address: 6-22-1 Mure, Mitaka-shi, Tokyo 181-8622 Japan

selected conformity  
assessment procedure: Annex II excluding (4)

European Representative: Hitachi Medical Ultrasound Logistics,  
Address: Zweigniederlassung der Hitachi Medical Systems Europe Holding AG  
Carl-Zeiss-Strasse 5  
D-72555 Metzingen  
Germany

Product: ***Transrectum Mechanical Radial Scanner***

Model Code: ***ASU-67***

Classification (MDD, Annex IX): II a

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 : **202A6925**

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

Date: **31. May. 2012**

Signature: MASAOKI HIRAKAWA

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