

DECLARATION OF CONFORMITY

Manufacturer: Aloka Co., Ltd.
Address: 22-1 Mure 6-chome, Mitaka-shi, Tokyo 181-8622 Japan
European Representative: Aloka Co., Ltd. Europe Office
Address: Zandsteen 11-13 2132MZ, Hoofddrop, The Netherlands
Product: Transrectum Puncture Electronic Convex Probe
Model Code: **UST-670P-5**
Classification (MDD, Annex II): II a

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

DIRECTIVES

General applicable directives:

Medical Device Directive : Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/ECC).

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

EN 60601-1(1988) + A1(1991) +A2(1995)
EN 61157(1992), EN 30993-1 (1993)

Other Standards :

IEC 60601-1-1(1992) + A1(1995)
ISO 10993-1 (1992)

Notified body : TUV Product Service GmbH, Ridlerstr. 31, D-80339 Munchen, Germany

EC Certificate : No. G1 96 01 22532 002 (ANNEX II , Clause 3 : MDD)

Start of CE marking: SN: *M00721*

Place: Tokyo Works, Aloka Co., Ltd. , Ueda Factory, Aloka Co., Ltd.

Date: *01 Dec 1999*

Signature:



Name of issuer : Kazuo Suzuki

Position : General Manager of Quality Assurance Department