

# CERTIFICATE

No. QZZ 04 05 25304 003



Holder of Certificate:



**Diagnostic Ultrasound Europe B.V.**

Lage Dijk 14  
3401 RG IJsselstein  
The Netherlands

Facility(ies):

Diagnostic Ultrasound Europe B.V.  
Lage Dijk 14, 3401 RG IJsselstein, The Netherlands

Certification Mark:



Scope of Certificate:

**Marketing, sales, service and distribution  
of medical devices and accessories as  
out of DxU Diagnostic Ultrasound Corporation**

Applied Standard(s):

**EN ISO 13488:2000**  
Quality Systems - Medical Devices -  
Particular Requirements for the Application of  
**EN ISO 9002:1994**

The Certification Body of TÜV PRODUCT SERVICE GMBH certifies that the company mentioned above has established and is maintaining a quality system which meets the requirements of the listed standards. See also notes overleaf.

Report No.:

70068509

Valid until:

2006-07-14

Date, 2004-06-21



TÜV PRODUCT SERVICE GMBH  
Zertifizierstelle  
Ridlerstraße 65 D-80339 München  
Gruppe TÜV Süddeutschland

Akkreditiert durch



Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten

vertreten im



ZLG-ZQ-999.98.12-46

# EC Certificate

No.: G1 01 11 45683 001



Decision according to Annex II, Clause 3 of Council Directive 93/42/EEC concerning medical devices.

The Certification Body of TÜV PRODUCT SERVICE certifies that

**Diagnostic Ultrasound Corporation**  
21222 30<sup>th</sup> Drive SE, Suite 120  
Bothell, WA 98021  
USA

with the authorized EC representative:

**Diagnostic Ultrasound Europe B.V**  
Lage Dijk 14  
3401 RG Ijsselstein  
The Netherlands

in the facility(ies)

- **Diagnostic Ultrasound Corporation**  
21222 30<sup>th</sup> Drive SE, Suite 120  
USA – Bothell, WA 98021
- **Research and Development Laboratory**  
16932 Woodinville - Remond Road  
USA – Woodinville, WA 98072

for the product(s)/product category(ies)

## Ultrasound and Doppler Systems for Urology and Vascular Diagnostics

maintains a quality system which ensures that the products conform with the essential requirements of the Directive, which apply to them at every stage from design to final controls.

Reasoned assessment see audit report no.: AM100844-101.

Provided the agreed periodical surveillance is carried out, this certificate is valid until 2006-11-18.

Released with the above mentioned certificate number by the Certification Body of TÜV PRODUCT SERVICE.

Department: MHS-STC / jw-tgu  
Date: 2001-11-19



TÜV PRODUCT SERVICE GMBH is Notified Body according to Council Directive 93/42/EEC concerning medical devices with identification no. 0123.