

Declaration of Conformity

We declare under our sole responsibility that the following product to which this declaration relates is in conformity with the standards or other normative documents under the provisions of Medical Devices Directive 93/42/EEC and RoHS Directive 2011/65/EU.

Common name:	Diagnostic Ultrasound Imaging Equipment
Model name:	UF-890AG
Classification:	Class IIa (according to Annex IX of Directive 93/42/EEC)
Categories:	8 (according to Annex I of Directive 2011/65/EU)
Accessories:	See Appendix 1
Manufacturer:	Fukuda Denshi Co., Ltd. 3-39-4 Hongo, Bunkyo-ku, Tokyo, Japan
Location of design:	Fukuda Denshi Co., Ltd. Hongo Office 2-35-8 Hongo, Bunkyo-ku, Tokyo, Japan
Location of production:	Fukuda Denshi Co., Ltd. Shiroi Factory 305-1 Naka, Shiroi-shi, Chiba, Japan Fukuda Denshi Finetech Sendai Co., Ltd. 5 Technohills, Taiwa-cho, Kurokawa-gun, Miyagi, Japan
Applied Annex:	Annex II of Directive 93/42/EEC (Accessories except Option Probes: Annex VII of Directive 93/42/EEC)
Notified Body:	BSI Group The Netherlands B.V. (2797) Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands
Certificate No.:	CE 01612

Note: BSI's CE Certificate covers only MDD 93/42/EEC Class IIa and IIb, but not RoHS Directive 2011/65/EU and Class I accessories.

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Following products are in conformity with the provisions of Medical Devices Directive 93/42/EEC and RoHS Directive 2011/65/EU starting with the below mentioned S/N.

Model	S/N
UF-890AG	50200001 ~
UF-890AG-CWD	50000001 ~
UF-890AG-CPG	50000001 ~
UF-890AG-SCU	50000001 ~
UF-890AG-MWM	50000001 ~
UF-890AG-STE	50000001 ~
UF-890AG-LCL	50000001 ~
UF-890AG-4D	50000001 ~
UF-890AG-EOP	50000001 ~
UF-890AG-TAC	50000001 ~
UF-890AG-HQV	50000001 ~
UF-890AG-IMT	50000001 ~
FUT-LG308-16A	50000381 ~

Appendix 1 (List of Accessories)
Standard Accessories

Common name	Model
Power cord	CS-18
Power cord	CS-24
Sonic gel	OJ-22
Operation manual	4L011228*
Acoustic output reporting table	4L011233*
Installation Manual	4L011297*

* means revision number

Related Products
Option Probes (UF-890AG)

Common name	Model
Electronic sector probe	FUT-SA162-5P
Electronic linear probe	FUT-LA385-12P
Electronic convex probe	FUT-CA602-5P
Electronic convex probe	FUT-TVG114-7A
Electronic micro convex probe	FUT-CA144-9P
4D convex probe	FUT-CVA403-6P
Electronic sector probe	FUT-SG125-8P
Electronic sector probe	FUT-SA161-5P
Electronic linear probe	FUT-LG308-16A

Options (UF-890AG)

Common name	Model
Biopsy needle guide holder	FUT-PAD16A
Biopsy needle guide holder	FUT-PAD60C
Biopsy needle guide holder	FUT-PVG11A
Biopsy Needle guide holder	FUT-PAD14A
Biopsy Needle guide holder	FUT-PAD30A
Recorder tray	UF-890AG-RTY
CW Doppler	UF-890AG-CWD
Cardiac package	UF-890AG-CPG
DICOM storage SCU	UF-890AG-SCU
DICOM modality worklist	UF-890AG-MWM
Stress echo	UF-890AG-STE
Long cine loop	UF-890AG-LCL
4D package	UF-890AG-4D
Easy Optimize	UF-890AG-EOP
Trapezoid & Compound	UF-890AG-TAC
High Quality View	UF-890AG-HQV
Auto IMT measurement	UF-890AG-IMT
