

MANUFACTURER'S DECLARATION OF CONFORMITY

AUSTRALIAN THERAPEUTIC GOODS (MEDICAL DEVICES) REGULATIONS 2002 FULL QUALITY ASSURANCE PROCEDURE

This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian

Therapeutic Goods (Medical Devices) Regulations 2002 relating to the stated devices

Reference: Not Applicable

Manufacturer's Name: Weinmann Geräte für Medizin GmbH+Co. KG

Business Address: Kronsaaßweg 40, 22525 Hamburg, Germany

Medical Device(s): WM 5074 Transparent mask, size 5; WM 5082 Transparent mask, size 3; WM 5086 Transparent mask, size 1

Classification: IIa, classification rule no. 2 according to Directive 93/42/EEC

GMDN Code and Term: 36066; Mask, resuscitation

Scope of Application: All devices are manufactured and tested according to the applicable Quality Assurance Procedures. The serial numbers of the devices are documented in the device history record.

Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied.

Full Quality Management System Certificate:

EN ISO 13485:2003; Certificate number SX 60014975 0001. Issue date July 03, 2006. Issued by TÜV Rheinland Product Safety GmbH to Weinmann Geräte für Medizin GmbH+Co. KG.

EN ISO 9001:2000; Certificate number SY 60014976 0001. Issue date July 03, 2006. Issued by TÜV Rheinland Product Safety GmbH to Weinmann Geräte für Medizin GmbH+Co. KG.

EC Certificate – Full Quality Assurance System Approval Certificate (Annex II, Article 3 of the Directive 93/42/EEC on Medical Devices); Certificate number HD 60014972 0001. Issue date July 03, 2006. Issued by TÜV Rheinland Product Safety GmbH to Weinmann Geräte für Medizin GmbH+Co. KG. EC code number 0197.

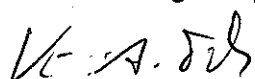
Design Examination Certificate:

Not applicable (not class III device). Applicable requirements included in the scope of above certificates

Standards Applied:

based on EN 794-3

Authorised Signatory:



Dr. K.-A. Feldhahn
President
Chief Technology Officer

18-08-2007
Date