

MATTES

INSTRUMENTE GmbH
MEDIZINTECHNIK

Mattes-Instrumente GmbH · Haldenstr. 27 · D-78532 Tuttlingen

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DECLARATION OF CONFORMITY

Within the meaning of the EC Directive for Medical Products 93/42 EEC dated 14 June 1993

Name of the manufacturer : MATTES INSTRUMENTE GMBH

Address of the manufacturer : HALDENSTRAßE 27 * D – 78532 TUTTLINGEN

MATTES INSTRUMENTE GMBH hereby declares that its PRODUCTS labelled <CE> and manufactured and/or distributed under the name "MATTES INSTRUMENTE" comply with the relevant provisions of the European Directive 93/42 EEC, Annex VII and the German Medical Products Law (Medizinproduktegesetz – MPG)

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

General surgical instruments / dental instruments / sterilisation containers / instruments for skeletal surgery (osteosynthesis instruments).

This declaration is drawn up on the basis of the certified Quality System (DIN EN ISO 9001 / DIN EN 46001 No.Q1Z 99 12 35192 002) of MATTES INSTRUMENTE GMBH Tuttlingen/Nendingen in conformity with Annex VII of the Directive 93/42 EEC, issued by the manufacturer, Mattes Instrumente GmbH (manufacturer makes its own declaration for Class I products).

Grounds in accordance with Annex IX, Rule 1 for products which do not come into contact with tissue or bodily fluids (non-invasive for Class I products <<CE>>)

This declaration applies on the basis of the certified Quality System DIN EN ISO 9001 / DIN EN 46001 - 93/42 EEC ANNEX VII to all MATTES INSTRUMENTS PRODUCTS labelled <<CE>>.

Grounds for the decision in accordance with 93/42 EEC Annex VII

Revision No. 2 dated 14.12.1999

Signature of the manufacturer :

Tuttlingen/Nendingen dated 14.12.1999

(signature)

Die gelieferte Ware bleibt unser Eigentum bis zur völligen Bezahlung. Erfüllungsort für Lieferung und Zahlung ist Tuttlingen.

USt-Id-Nr.: DE 142928321

Banken: Kreissparkasse Tuttlingen (BLZ 643 500 70) Konto 53 930