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DECLARATION OF CONFORMITY

(Annex VII for MDD devices)

MANUFACTURER SECURMED SPA
VIA MONTE GRAPPA 2/G
36016 THIENE –VI
ITALY

FACILITY: **Località Piane della Nocella SP 262**
64012 CAMPLI –TE- ITALY

PRODUCT single use sterile Guedel Cannula

CLASSIFICATION class I sterile with measuring function of medical devices, Rule 1 of annex IX of the *Council Directive 93/42 EEC*.
CONFORMITY ASSESSMENT ROUTE annex V + annex VII of MDD

We undersigned SECURMED SPA, manufacturer of "single use non sterile Guedel Cannula"**,** *declare that mentioned products meet the provisions of the Council Directive 93/42 EEC for medical devices* as amended by Directive 2007/47/EC*. All supporting documentation is retained under the premises of the manufacturer.*

STANDARDS APPLIED :

General Standards: Medical Devices Directive 93/42 CEE, Directive 2007/47/EC, UNI EN ISO 9001:2008,ISO 13485 :2003, UNI CEI EN ISO 14971 , UNI CEI EN 980

Technical Standard: ISO 8669/2: 1998

Notified Body : TÜV Product Service GmbH
65,Ridlerstrasse
80339 Munich – Germany

TÜV identification number:0123

START OF CE-MARKING 1998-06-02
EC CERTIFICATE N° G2S 036310 0038 valid until :2024-06-03
PLACE, DATE of ISSUE Thiene , 2018-06-12
VALIDITY of declaration of conformity: 2024-06-03

Signature : SECURMED SPA
Legal Representative

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