



CE DECLARATION OF CONFORMITY

According to Annex II to Council Directive 93/42/EEC

We, Fountain Head Marketing Inc.
14410 Saratoga Pass
San Antonio, Texas 78254--1860 USA

Declared under exclusive responsibility that the Quality Management System of Fountain Head Marketing and the below medical devices are in compliance with the requirements of the Council Directive 93/42/EEC.

Classification: Class I (according to Annex IX to Council Directive 93/42/EEC)

Brand: Romet Electronic Larynx
Models: R100, R210, R310, R440 - Black, Grey, White, Gold

GMDN Code: 30910

This Declaration also covers accessories.

Any modification of the medical device not authorized by us will invalidate this Declaration.

The conformity of the full Quality Management System is certified by:

PONY TESTING International Group
Building 35, No. 680, Guiping Road, Xuhui District, Shanghai, China

Standards Applicable: EN 60601-1-1:2007 EN 60601-1-2:2006

Place and date: San Antonio, Texas 78254 2/19/16

Name: Tom Dodson, President
Director of Quality Control and R&D

This Declaration will be renewed on any significant change of product range or latest on an annual basis. For condition of guarantee and liability please refer to our General Conditions for Sale.

Greece Authorized
Representative:

Attn:
Mr. Vagelis Tzigalidis
FLEXIMED AE
Michailidi Alexandrou 19
552 36 Panorama Thessaloniki
Greece Tel : +30 2310 328168
Fax: +30 2310 328187
email: info@fleximed.gr
www.fleximed.gr