EC Declaration of Conformity

Manufacturer:

Sybaritic, Inc.
9220 James Ave S
Minneapolis, MN 55431

whose single Authorized Representative:

GBM Authorised Representative Ltd.
The White House, 2 Meadrow
Godalming, GU7, 3HN
Surrey, England

We, the manufacturer, herewith declare that the products

Trio iShape

meet the provisions of Directive 93/42/EEC which apply to them.

The medical device has been assigned to class IIa according to Annex IX of the Directive 93/42/EEC. It bears the mark

CE 0197

The product concerned has been designed and manufactured under a quality management system according to Annex II of Directive 93/42/EEC.

Compliance of the designated product with the Directive 93/42/EEC has been assessed and certified by the Notified Body

TÜV Rheinland LGA Products GmbH
Tillystraße 2, 90431, Nürnberg, Germany
Certificate No.: HD 60032708 0001
Issue date: 12-16-2010
Expiry date: 03-01-2015

following the procedure relating to the EC Declaration of Conformity set out in Annex II of Directive 93/42/EEC.

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark

The above mentioned declaration of conformity is exclusively under the responsibility of

Company: Sybaritic, Inc.
Address: 9220 James Ave S, Minneapolis, MN 55431

Minneapolis, MN December 15, 2011 — Regulatory Affairs Manager
Place, date — *Legally binding signature, Function*

Form: 709 Revision Level: A