

EC DECLARATION OF CONFORMITY

Manufacturer **Sivantos GmbH**
Henri-Dunant-Strasse 100
91058 Erlangen
Germany

Brand: **Siemens**
Series: Otoplastic
Type of Device: Otoplastic / Earmoulds
Product Identification:

Otoplastic

We declare under our sole responsibility that above products are in conformity with the following Directives:

Council Directive 93/42/EEC as amended by Dir. 2007/47/EC (MDD)

Conformity assessment procedure: Annex II without chapter II.4 of 93/42/EEC
Notified Body: TÜV SÜD Product Service GmbH, Notified Body No.: NB 0123
Ridlerstr. 65, 80339 München, Germany
Classification of device: **Class IIa** (according to Annex IX to Council Directive 93/42/EEC)
The products meet the applicable standards and the basic requirements of the Directive 93/42/EEC Annex I.

Council Directive 2011/65/EU (RoHS)

Relevant Harmonized Standards: EN 50581:2012

Place and valid from date Erlangen, January 19th, 2017

Name i.V. Dr. Heike Heuermann
(Research & Development)

i.V. Rainer Walther
(Quality Management)

Signature 



This declaration will be renewed on any significant change of product, product range, standards and laws.