



Structo[®]
Empowering Dental with 3D

EU DECLARATION OF CONFORMITY

Manufacturer:	Structo Pte. Ltd.
Sales & Distribution Address:	114 Lavender Street, #07-53 CT Hub 2, Singapore 338729
Manufacturing Address:	155 Kallang Way #05-09/10, Singapore 349244

This is to declare that the product described hereafter:

Product Name : Structomer[®] Guide
Product Number : 15001
UMDNS Code* : 11930 (Guides, Drill)
Size : 1000g
Scope of Application : All lots

**UMDNS code is applicable to finished product made using Structomer[®] Guide material.*

has been classified as Class I (Annex IX, Rule 5) and is in conformity with the essential requirements and provisions of the Council Directive 93/42/EEC for medical devices as amended by Directive 2007/47/EC;

and is in conformity with the following harmonized standards:

Standards Applied: EN ISO 14971:2012
EN ISO 10993-1:2009
EN ISO 10993-5:2009
EN ISO 10993-10:2010
EN ISO 15223-1:2016
EN 1041:2008
EN 62366:2008

and is subject to the procedure set out in Annex VII of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC.

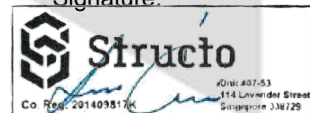
This declaration is being made on the basis of the quality management certificate EN ISO 13485:2016 (Certificate Registration No.: SX 60123680 0001, valid until 2020-11-16) delivered by:

TÜV Rheinland
LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Germany

This declaration of conformity is issued under the sole responsibility of Structo Pte. Ltd. The document together with technical documentation are the basis for awarding the product with **CE** mark.

Singapore, 03 May 2018

Signature:



Ana Ciric, PhD
Management Representative

Structo Pte. Ltd.
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