

# EU DECLARATION OF CONFORMITY

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

This is to declare that the product described hereafter:

**Product Name** : Structomer<sup>®</sup> Tray  
**Product Number** : 16001  
**UMDNS Code\*** : 16350 (Trays, Impression, Dental)  
**Size** : 1000g  
**Scope of Application** : All lots

*\*UMDNS code is applicable to finished products made using Structomer<sup>®</sup> Tray 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:

<b>Standards Applied:</b>	EN ISO 14971:2012	EN ISO 15223-1:2016
	EN ISO 10993-1:2009	EN 1041:2008
	EN ISO 10993-5:2009	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.

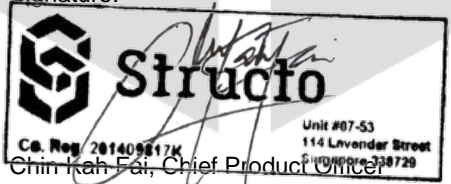
This declaration is being made on the basis of the quality management certificate EN ISO 13485:2016 (Certificate Registration No.: SX 60123680 0001, valid until 2020-11-16) delivered by:

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, 13 April 2018

Signature:



**Structo**  
Unit #07-53  
114 Lavender Street  
Singapore 338729  
Co. Reg. 201409817K  
Chin Kah Fai, Chief Product Officer