



EC Declaration of Conformity

Manufacturer's name: Stratasys Ltd.
Manufacturer's address: 1 Holtzman St.
 Science Park,
 Rehovot 7612401, Israel

Material Name: MED625FLX™, CL: Flexible Clear Biocompatible Material

Description of material:

The material "MED625FLX™, CL" (further called MED625FLX™) is a UV-curable polymeric material to be used in a rapid prototyping (3D printing) process using 3D printing devices of Stratasys GmbH. 3D-printed final medical devices are then produced by numerous medical device manufacturers whereby the exact intended purpose of such devices is unknown to Stratasys GmbH. Therefore, this Biological Evaluation Report / Overall Biological Risk Assessment is intended to, more generally, cover the following medical purposes:

- "Surface device" with "long term" (> 30 days) contact to "intact skin"
- "Surface device" with "limited" (≤ 24 hours) contact to "mucosal membranes"
- "Surface device" with "limited" (≤ 24 hours) contact to "breached or compromised surfaces"
- "External communicating device with "limited" (≤ 24 hours) contact to "tissue/bone/dentin"
- "Implant device" with "limited" (≤ 24 hours) contact to "tissue/bone".

Printer	Support Type	Mode	Support removal	Cleaning
Objet 260/500 Dental Selection Objet 260 Dental	SUP705/705B/706B SUP706	HS &DM HS	Water Jet + 1%NaOH	IPA
J750 Digital Anatomy Printer J750 J735 J720 Dental Printer	SUP705/705B SUP706/706B	HS, HM and HQ		
J55 J5 DentaJet	SUP710/711	HQS and HS – Matt models only	Water Jet + 1% NaOH	IPA



J850™/ J850™Pro/ J850™Prime J835™ J826™ /J826™Prime/ J850 Digital Anatomy Printer	SUP705/705B/706/706B	HQ, HS and HM	Water Jet + 1% NaOH	IPA
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MED625FLX™ can be sterilized using steam (132 °C for 4 minutes) and gamma irradiation (25- 50 kGy)

Directives compliance:

Class I, IIa or IIb medical devices under the Directive
Medical devices: 93/42/EEC include
change directive 2007/47/EC (Annex IX)

Harmonized standards to which conformity is declared:

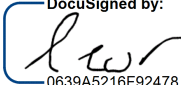
EN ISO 10993-5:2009
EN ISO 10993-10:2013
EN ISO 10993-11:2018
EN ISO 10993-18:2020
EN ISO 10993-17:2009
EN ISO 10993-3:2014
USP <88>

For sample preparation and dosing EN ISO 10993-12:2012, is applicable.

We the undersigned hereby declare that the polymerized MED625FLX™, CL to which this declaration relates is in conformity with the above directives and Standards.



Authorized person:

Signature: 
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Full Name: Lior Zonder
Position: Head of PolyJet Materials R&D
Date of issue: January 2022
Place of issue: Rehovot, Israel

**Authorized representative located
Within the EU community:**

Signature: *Andreas Langfeld*
Full Name: Andreas Langfeld
Position: President Stratasys EMEA
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