



EC Declaration of Conformity

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

Material Name: MED610™, Rigid Clear Biocompatible Material with SUP706 / SUP706B / SUP710 / SUP711

Description of material:

MED610 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" (\leq 24 hours) contact to "mucosal membranes"
- "Surface device" with "limited" (\leq 24 hours) contact to "breached or compromised surfaces"
- "External communicating device with "limited" (\leq 24 hours) contact to "tissue/bone/dentin"
- "Implant device" with "limited" (\leq 24 hours) contact to "tissue/bone".

Printer	Support Type	Mode	Support Removal	Cleaning
Alaris/Desktop Objet30 OrthoDesk Objet30 Dental Prime Objet30 Pro Objet30 Prime	SUP706/706B	HS & HQ and Draft	Cleaning station with Alkaline Cleaning Solution 2% NaOH + 1% Na ₂ SiO ₃ ("Jaccuzzi") and neutralization	IPA
			Water Jet + 1% NaOH	

Printer	Support Type	Mode	Support Removal	Cleaning
Objet260 Connex1/2/3 Objet260 Dental Objet260 Dental Selection Objet350 Connex1/2/3 Objet500 Connex1/2/3 Objet500 Dental Selection	SUP706/706B	HS, HQ and DM*)	Cleaning station with Alkaline Cleaning Solution 2% NaOH + 1% Na ₂ SiO ₃ ("Jaccuzzi") and neutralization	IPA
Connex260/350/500 Objet260 Connex	SUP706/706B	HS, HQ and DM*)	Water Jet + 1% NaOH	
Eden250/260V/260VS/ 260VSDentalAdvantage/3 50/350V/500V	SUP706/706B	DM*) and HQ	Cleaning station with Alkaline Cleaning Solution 2% NaOH + 1% Na ₂ SiO ₃ ("Jaccuzzi") and neutralization + glycerol	
J750 Digital Anatomy Printer J750 J735 J720 Dental Printer	SUP706/706B	HQ, HS and HM	Water Jet + 1% NaOH Cleaning station with Alkaline Cleaning Solution 2% NaOH + 1% Na ₂ SiO ₃ ("Jaccuzzi") and neutralization	IPA
J5MediJet™ J5DentaJet™	SUP710/711	HQS and HS	Water Jet + 1% NaOH	IPA
J850™/ J850™Pro/ J850™Prime J835™ J826™ /J826™Prime/ J850 Digital Anatomy Printer	SUP706/706B	HQ, HS and HM	Water Jet + 1% NaOH	IPA

*) Digital Mode (DM) when available on printers

MED610™ can be sterilized using steam (132 °C for 4 minutes), gamma irradiation (25-50 kGy) and EtO (740mg EtO/l for 6h at 45°C and 40-90% RH, followed by degassing for 48h (1 sterilization cycle), respectively for 96h (2 sterilization cycles).

**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)

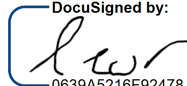
Harmonized standards to which conformity is declared:

EN ISO 10993-5:2009
ISO 10993-23:2021
EN ISO 10993-10:2013
EN ISO 10993-11:2018
ISO 10993-18:2020
EN ISO 10993-17:2009
ISO/TS 21726; EFSA
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 MED610™ to which this declaration relates is in conformity with the above directives and Standards.

Authorized person:

DocuSigned by:

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Signature:
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:**

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