



Design Dossier – Part B

Sterile Absorbable Hyaluronic Acid
Dermal Filler

Doc. No. BP-DDB-001

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13.0 Declaration of Conformity (DoC)

Document No. Input the document number.
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EC Declaration of Conformity

We herewith declare that the undermentioned products meet the provisions of the Council Directive 93/42/EEC as amended by Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer.

Product Name: **Sterile Absorbable Hyaluronic Acid Dermal Filler**
Brand Name : **SkinPlus-HYAL[®], HyalDew[®], HELENE[®], stilea[®], DENE[®]**
Model Name: **SkinPlus-HYAL[®] 60, SkinPlus-HYAL[®] 65, SkinPlus-HYAL[®] 70, SkinPlus-HYAL[®] 100**

Classification : **Class III (Council Directive 93/42/EEC as amended by Directive 2007/47/EC, Annex IX Rule 8)**

Conformity Assessment Route : **Annex II, Including Section 4, Council Directive 93/42/EEC as amended by Directive 2007/47/EC**

Notified Body : **Sztest Teknik Kontrol ve Belgelendirme Hizmetleri Ticaret Limited Şirketi**
[Notified Body No. : 2195]
Yukarı Dudullu Mahallesi Nato Yolu Caddesi Çam Sokak No: 7 Ümraniye/İSTANBUL, Turkey

Standards applied : **EN ISO13485:2012/AC:2012, EN ISO14971:2012, EN 14155:2011, EN ISO10993-1:2009, EN 17665-1:2006, EN62366:2008, EN ISO14630:2009, ISO14644-1:1999, EN ISO11607-1:2009, EN ISO11737-1:2006/AC:2009, EN1041:2008, EN980:2008, EN ISO15223-1:2012, MEDDEV 2.7/1 Rev.3, MEDDEV 2.12/1 Rev. 8, MEDDEV 2.12/2 Rev.2, EP 8.0:2015**

EC Representative : **INTERNATIONAL MEDICAL EXPERT, s.r.o.**
Miloticka 458/12, Praha-Zlicin, 155 21, Czech Republic
Tel : +420226208268, +420732735009

GMDN Code. : **17876 [Tissue reconstructive material, synthetic, hyaluronic acid]**
EC Certificate : **2195-MED-1418802-D01**
EC Certificate Expiry Date : **July 16, 2019**



Signature :

Place of Issue : **Daejeon, Korea**
Date of Issue : **Start of CE Marking**

Hyun-Kyu Jung/ CEO

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