EC Design Examination Certificate: Certificate US07/1125

ANIKA Therapeutics, Inc.

32 Wiggins Avenue,
Bedford, MA, 01730, United States

Device Identification:
Monovisc™ 4ml volume.

Intended Purpose of Device:
Sterile Cross-linked Sodium Hyaluronate Viscoelastic Supplement for Intra-articular use in the knee.
Intra articular use in other synovial joints is restricted to post market clinical study use only.
has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on Medical Devices Annex II, section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 30 May 2018 until 27 September 2022
Issue 12

Certification is based on report number(s) WWPCI 600593 dated 21 May 2018

Addenda to that report have been issued on the following dates:

Addendum Date	Reason for Addendum

Authorised by

SGS United Kingdom Limited, Notified Body 0120
202B Worle Parkway, Weston-super-Mare, BS22 6WA, UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS EC 01 0311

EC Certificate Full Quality Assurance System: Certificate US96/7957

The management system of

ANIKA Therapeutics, Inc.

32 Wiggins Avenue,
Bedford. MA. 01730. United States
has been assessed and certified as meeting the requirements of

Directive 93/42/EEC

on medical devices, Annex II (excluding Section 4)

For the following products

Sterile Orthovisc® Sodium Hyaluronate and Sterile Orthovisc® mini Sodium Hyaluronate for intra-articular injection;
Sterile Optivisc™ Sodium Hyaluronate for use during surgery in the anterior and posterior segments of the human eye including cataract extraction and IOL implantation;
Sterile Incert® -S Sodium Hyaluronate barrier gel for prevention of post surgical adhesions;
Sterile Monovisc™ Sodium Hyaluronate Viscoelastic Supplement for intra-articular use;
Sterile Elevess™, Sterile Elevess™Light, Sterile Hydrelle™and Sterile Hydrelle™ Fine for correction of soft tissue contour deficiences;
Sterile Anikavisc Sodium Hyaluronate for use during surgery in the anterior and posterior segments of the human eye including cataract extraction and IOL implantation.

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 2 May 2015 until 6 September 2020 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 9 September 2017
Issue 13. Certified since 6 September 1996

Certification is based on reports numbered WW/ME 05195

Authorised by

SGS United Kingdom Ltd. Notified Body 0120
2nd Floor, Parkway, Solihull Parkway, Birmingham Business Park, B37 7YA UK
t +44 (0)1934 822617 f +44 (0)1934 522137 www.sgs.com

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