SANOFI

EC Declaration of Conformity

Owner:	Genzyme Corporation 50 Binney Street Cambridge, MA 02142 USA
Manufacturer:	Genzyme Biosurgery, a division of Genzyme Corporation 1125 Pleasant View Terrace Ridgefield, NJ 07657 USA
European Representative:	Genzyme Europe B.V. Paasheuvelweg 25 1105 BP Amsterdam Netherlands

We herewith declare that:

SYNVISC® (hylan G-F 20) (1 x 2 mL),
SYNVISC® (hylan G-F 20) (3 x 2 mL), and
Synvisc-One® (hylan G-F 20) (1 x 6 mL)

are in conformity with Annex IX, Rule 8 and Rule 17 under the provisions of the EC Directive 93/42/EEC and amendment 2007/47/EC, which apply to them. Under the supervision of BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands, Tel: +31 20 346 0780, a Notified Body duly authorized by the Netherlands Competent Authority to carry out such assessments, and carrying the Notified Body number 2797.

This declaration is based on:

FM 701465 Certificate of Approval for the Quality Management System applicable to design and manufacture of medical devices for use in orthopaedic, tissue augmentation, ophthalmic and surgical applications in accordance with ISO 13485:2016

CE 542631 EC Design Examination Certificate for the Design Dossier for Synvisc/Synvisc-One Class III medical devices based on hylan A and hylan B, hyaluronan derivatives for the treatment of pain due to osteoarthritis, in conformity with Annex II, Clause 4 of the Medical Devices Directive 93/42/EEC and amendment 2007/47/EC

CE 537606 Approval of Conformity Certificate for the Quality Management System applicable to products manufactured as specified, in conformity with Annex II of the Medical Devices Directive 93/42/EEC and amendment 2007/47/EC

Name: Damian Lamarche
Title: Senior Manager
Department: Global Regulatory Affairs CMC Biologics

Signature: Damian Lamarche Date: 04 Sep 19