EC Design-Examination Certificate
Directive 93/42/EEC on Medical Devices, Annex II, section 4

Design Approval no. 3144-2013-CE-IND-D

Manufacturer name:
BioTech Ophthalmics Pvt. Ltd.

Manufacturer address:
Plot no. 555, 556, 557 Khatraj-Vadsar Road, Opp. Shubham Tex-o-pack, Khatraj, Tk. Kalol, Dist. Gandhinagar, Gujarat, India

Type of medical device and identification no.:	**Class of Medical Device:**
Biovisc Ortho: 2ml in PFS Biovisc Ortho Single: 2ml and 3 ml in PFS	III

Short description of the medical device:
Biovisc Ortho is a sterile, non-pyrogenic, viscoelastic fluid used as a temporary replacement and supplement for synovial fluid. Sodium Hyaluronate is the main ingredient in the device and is obtained from fermentation source. The indications of the device are – pain & restricted mobility as a result of degenerative or traumatic pathology in the knee or other synovial joints.
Biovisc Ortho Single – this has cross-linked Sodium Hyaluronate of concentration 30mg/ml. The manufacturer claims that this device reduces the number of intra-articular injections and increase the intervals between injections. The concentration of HA used is 30mg/ml.
The devices are manufactured under LAF of Class 100 in a Class 10000 clean room.

This is to certify that the *medical device* fulfils the relevant requirements for Directive 93/42/EEC concerning medical devices.

Limitations:
Any changes in the Design shall immediately be reported to Det Norske Veritas Certification AS in order to examine whether this Certificate remains valid. Annual Periodical Audits will be held to verify the validity of this Certificate.

The examined documents are filed under: PRJC-534687-2015-MSL-IND

This certificate is valid until: 31 May 2021

for DNV GL BUSINESS ASSURANCE NORWAY AS Tone Kolpus Tone Kolpus *Certification Manager*	Høvik, 31 May 2016 Aud Løken Eiklid *Technical Reviewer*

This Certificate has been digitally signed. See www.dnv.com/digitalsignatures for more info

This Certificate is valid until the date specified. Any significant changes in the design or construction of the products, the quality system or amendments to the Directive may render this Certificate invalid at an earlier date. The product liability rests with the manufacturer or his representative in accordance with Council Directive 85/374/EEC