



DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 3144-2013-CE-IND Rev 1.0

This Certificate consists of 3 pages

This is to certify that the Quality Management System of

BioTech Ophthalmics Pvt. Ltd.

Plot no. 555, 556, 557 Khatraj-Vadsar Road, Opp. Shubham Tex-o-pack, Vill Khatraj, Tal. Kalol, Dist. Gandhinagar, Gujarat, India

for design, production and final product inspection/testing of

Sterile Solutions for Osteoarthritis use

has been assessed with respect to

the conformity assessment procedure described in Article 11.1.a and Annex II (Module H1) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date:

Høvik, 31 May 2016

This Certificate is valid until:

31 May 2021

For DNV GL BUSINESS ASSURANCE
NORWAY AS



Tone Kolpus
Certification Manager

Notified Body No.:
0434

Aud Løken Eiklid
Technical Reviewer

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

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

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