

Declaration of Conformity

Biovico Sp. z o.o.
ul. Hutnicza 15 B
81-061 Gdynia, Poland

Product details

Product category	Lubricating Jellies, UMDNS Code 12-401
Product designation	Hyaluronic acid, intra-articular gel
Indication of use	Orthopaedics: Viscosupplementation
Product name	Biolevox ONE
Types	2.5 %
Remarks	bacterial fermentation - non animal
Sterilization	Steam sterilization
Lot no.	XXX until expiry date of certificate
Classification according to 93/42/EEC:2007-09-05, annex IX	III Rule 8

Assessment details

Notified body	ECM, Bismarckstr. 106, D-52066 Aachen, Germany		
Identification number	0481		
Route of directive 93/42/EEC:2007-09-05	II.3 and II.4		
Certificates	Z/18/04306E		
Date of issue 24 th September 2018	Date of expiry	18 th July 2023	

We declare under sole responsibility of Biovico that the products described above are in compliance with annex I of directive 93/42/EEC amended by 2007/47/EC.

Gdynia, 24th September 2018

WICEPREZES ZARZADU

Konrad Wiland
Vice-President