HYALTECH
A Carl Zeiss Meditec Company

DECLARATION OF CONFORMITY CERTIFICATE

MANUFACTURER:	Hyaltech Ltd. Starlaw Business Park Livingston, EH54 8SF, United Kingdom
PRODUCT:	Fermathron Plus Synovial Viscosupplement Device Product number: 230001 Biomet Reference number: 236381 - INT GMDN code: P44757
CLASSIFICATION:	Class III; Annex IX, Rule 8.
CONFORMITY ASSESSMENT ROUTE:	Annex II

We herewith declare that the above mentioned product meets the provisions of the Council Directive 93/42/EEC for medical devices. All supporting documentation is retained under the premises of the manufacturer.

STANDARDS APPLIED:	List of standards for which documented evidence for compliance can be provided
NOTIFIED BODY:	DEKRA Certification B.V. Meander 1051 6825 MJ Arnhem P.O. Box 5185 6802 ED Arnhem The Netherlands Notified body number: 0344
EC CERTIFICATE:	2011354CE06
DESIGN EXAMINATION CERTIFICATE:	2011354DE04
START OF CE MARKING:	2008
PLACE, DATE OF ISSUE:	Livingston, 10/2015

SIGNATURE: ..... 16/10/2015.

Ian McKeating
Operations manager
For and on behalf of Hyaltech Ltd.

SIGNATURE: 16/10/2015

Lesley Paice
Quality and Regulatory Affairs Manager
For and on behalf of Hyaltech Ltd.

Fermathron Plus - list of applicable standards

Standard Number	Title of Document
BS EN ISO 13485:2012	Medical devices – Quality Management Systems - Requirements for regulatory purposes
MDD 93/42/EEC and 2007/47/EC amendments	Medical Devices Directive
BS EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
MEDDEV 2.7.1 rev 3	Evaluation of Clinical Data - A guide for manufacturers and notified bodies
MEDDEV 2.12-1 rev 8	Guidelines on a medical devices vigilance system
BS EN ISO 14155:2011	Clinical investigations of medical devices for human subjects – Good clinical practice
BS EN ISO 14630:2012	Non-active surgical implants - General requirements
BS EN ISO 10993-1:2009	Biological evaluation of medical devices - Evaluation and testing within a risk management process
BS EN ISO 10993-2:2006	Biological evaluation of medical devices - Animal welfare requirements
BS EN ISO 10993-3:2014	Biological evaluation of medical devices - Tests for genotoxicity, carcinogenicity and reproductive toxicity
ISO 10993-5:2009	Biological evaluation of medical devices - Tests for *in vitro* cytotoxicity
BS EN ISO 10993-6:2009	Biological evaluation of medical devices - Tests for local effects after implantation
BS EN ISO 10993-7:2008	Biological evaluation of medical devices - Ethylene oxide sterilisation residuals
BS EN ISO 10993-10:2013	Biological evaluation of medical devices - Tests for irritation and skin sensitisation
BS EN ISO 10993-11:2009	Biological evaluation of medical devices - Tests for systemic toxicity
BS EN ISO 10993-12:2012	Biological evaluation of medical devices - Sample preparation and reference materials
BS EN ISO 10993-17:2009	Biological evaluation of medical devices - Establishment of allowable limits for leachable substances
BS EN ISO 10993-18:2009	Biological evaluation of medical devices - Chemical characterisation of materials
BS EN 285:2006 + A2:2009	Sterilisation - Steam sterilisers - Large sterilisers
BS EN 556-1:2001	Sterilisation of medical devices - Requirements for medical devices to be designated "STERILE" - Requirements for terminally sterilized medical devices
BS EN 556-2: 2015	Sterilisation of medical devices - Requirements for medical devices to be designated sterile - Requirements for aseptically processed medical devices
BS EN ISO 13408-1:2015	Aseptic processing of health care products - General requirements
BS EN ISO 13408-2:2011	Aseptic processing of health care products - Filtration
BS EN ISO 13408-4:2011	Aseptic processing of health care products - Clean-in-place technologies
BS EN ISO 13408-5:2011	Aseptic processing of health care products - Sterilisation in place
BS EN ISO 13408-6:2011 + A1:2013	Aseptic processing of health care products - Isolator systems
BS EN ISO 14937:2009	Sterilisation of health care products - General requirements for characterisation of a sterilising agent and the development, validation and routine control of a sterilisation process for medical devices
BS EN ISO 11138-1:2006	Sterilisation of health care products - Biological indicators - General Requirements
BS EN ISO 11138-2:2009	Sterilisation of health care products - Biological indicators - Biological indicators for ethylene oxide sterilisation processes

ISO 11135:2014	Sterilisation of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilisation process for medical devices
ISO 11737-1:2006/Cor 1:2007	Sterilisation of medical devices - Microbiological methods - Determination of a population of microorganisms on products
BS EN ISO 11737-2:2009	Sterilisation of medical devices - Microbiological methods - Tests of sterility performed in the definition, validation and maintenance of a sterilisation process
BS EN ISO 14644-1:1999	Cleanrooms and associated controlled environments - Classification of air cleanliness
BS EN ISO 14644-2:2000	Cleanrooms and associated controlled environments - Specifications for testing and monitoring to prove continued compliance with ISO 14644-1
BS EN ISO 14644-3:2005	Cleanrooms and associated controlled environments - Test methods
BS EN ISO 14644-5:2004	Cleanrooms and associated controlled environments - Operations
BS EN ISO 14644-6:2007	Cleanrooms and associated controlled environments - Vocabulary
ISO 14644-7:2004	Cleanrooms and associated controlled environments - Separative devices (clean air hoods, gloveboxes, isolators and mini-environments)
BS EN ISO 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - General principles and methods
BS EN ISO 14698-2:2003	Cleanrooms and associated controlled environments - Biocontamination control - Evaluation and interpretation of biocontamination data
BS ISO 21501-4:2007	Determination of particle size distribution - Single particle light interaction methods - Light scattering airborne particle counter for clean spaces
BS 5726:2005	Microbiological safety cabinets - Information to be supplied by the purchaser to the vendor and to the installer, and siting and use of cabinets - Recommendations and guidance
BS EN 1041:2008 + A1:2013	Information supplied by the manufacturer of medical devices
BS EN ISO 15223-1:2012	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - General requirements
BS EN ISO 11607-1:2009 +A1:2014	Packaging for terminally sterilised medical devices - Requirements for materials, sterile barrier systems and packaging systems
BS EN ISO 11607-2:2006 +A1:2014	Packaging for terminally sterilised medical devices - Validation requirements for forming, sealing and assembly processes
BS EN 20594-1:1994 incorporating ISO 594-1:1986	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - General requirements
ISO 594-2:1998 and BS EN 1707:1997	Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
BS EN ISO/IEC 17050-1:2010	Conformity assessment - Supplier's declaration of conformity - General requirements