Title: DECLARATION OF CONFORMITY: HYDROCYN aqua Gel		Bactiguard	
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EUROPEAN REPRESENTATIVE:	MR.G.ELKAYAM Obelis s.a Bd. General Wahis 53 1030 Brussels Belgium
MEDICAL DEVICE:	Wound Hydrogel Dressing
PRODUCT NAME:	HYDROCYN aqua Gel (refer Product Code Listing)
CLASSIFICATION:	IIb (Rule 4)
GMDN CODE:	47764
CONFORMITY ASSESSMENT ROUTE:	Annex II (Full Quality Assurance Excluding Section 4) Annex II (Design Dossiers Including Section 4)
STANDARD APPLIED:	Refer to the list of Standards (VMD-LS-008)
NOTIFIED BODY:	UDEM (Mutlukent Mahallesi 2073 Sokak No: 10 Umitkoy-CANKAYA, Ankara, Turkey)
IDENTIFICATION NUMBER:	CE 2292
(EC) CERTIFICATE (S):	M.2020.106.13752
(EC) DESIGN EXAMINATION: CERTIFICATE (S)	-
START OF CE-MARKING:	25th August 2020
VALIDITY OF CERTIFICATE (S):	27th May 2024
PLACE, DATE OF DECLARATION:	Penang, Malaysia, 25th August 2020

We, the manufacturer, are exclusively responsible for the declaration of conformity. The stated medical devices meet the provisions of the EC Directive 93/42/EEC - as amended directive by Directive 2007/47/EC. All supporting documentation is retained at the premises of the manufacturer.

Bactiguard (South East Asia) Sdn. Bhd. Co. No. 505559-U

Rohaniza Othman
Senior Manager- Quality Assurance and Regulatory Affairs
Date: 15/12/2023
Bactiguard (South East Asia) Sdn.Bhd.

Product	Classification
HYDROCYN aqua Gel	Class IIb

LIST OF HARMONIZED AND NON-HARMONIZED STANDARDS USED TO DEMONSTRATE COMPLIANCE TO THE EC DIRECTIVE 93/42/EEC / AS AMENDED BY 2007/47/EC

Category	Document Code	Scope
a) Product Design	European Pharmacopoeia 11th Edition	Wound Dressing
	Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC	Regulatory
	EN ISO 14971:2019/A11 :2021	Medical Devices - Application of Risk Management to Medical Devices
	IEC 62366-1:2015/A1:2020	Medical Devices - Application of Usability Engineering To Medical Devices
	MEDDEV 2.7/1 Rev 4, June 2016	Guidelines On Medical Devices, Evaluation of Clinical Data
	MEDDEV 2.12/2 Rev 2, 2012	Guideline on Medical Devices - Post Market Clinical Follow-up Studies. A Guide for Manufacturers and Notified Bodies.
	USP–NF 2023, Issue 1	Wound Dressing
b) Packaging	EN ISO 15223-1:2021	Medical Devices - Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements
	EN ISO 20417: 2021	Medical Devices - Information to be Supplied by The Manufacturer
	ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
	ICH Q1A(R2)	Stability Testing of New Drug Substance and Products
	ASTM D5276-19	Standard Test Method for Drop Test of Loaded Containers by Free Fall
	GHTF/SG3/N99-10:2004	Global Harmonization Task Force (GHTF) - Quality Management Systems - Process Validation Guidance
c) Manufacturing Quality System	EN ISO 13485:2016/A11 :2021	Medical Devices - Quality Management Systems - Requirements for regulatory purposes.
	Medical Device Directive Annex II (Full Quality Assurance Excluding Section 4)	Manufacturing Quality System
	Medical Device Directive Annex II (Design Dossiers Including Section 4)	Manufacturing Quality System

Category	Document Code	Scope
d) Manufacturing Environment	ISO 14644-1: 2015	Cleanrooms and associated controlled environments Part 1: Classification of air cleanliness by particle concentration.
	ISO 14644-4: 2022	Cleanrooms and associated controlled environments Part 4: Design, construction and start-up.
	EN ISO 14698-1:2003	Cleanrooms and associated controlled environments - Biocontamination control - Part 1:General Principles and methods .
	ISO 14698-2:2003/Cor 1:2004	Cleanrooms and associated controlled environments- Biocontamination control - Part 2: Evaluation and interpretation of biocontamination data
e) Chemical, Physical and Biological Properties	EN ISO 10993-1:2018	Biological evaluation of medical devices. Part 1: Evaluation and testing within a risk management process.
	EN ISO 10993-2:2022	Biological evaluation of medical devices- Part 2: Animal welfare requirements.
	EN ISO 10993-3:2014	Biological evaluation of medical devices- Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
	EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
	EN ISO 10993-12:2021	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
	EN ISO 10993-23:2021	Biological Evaluation of Medical Devices -Test for Irritation
	EN ISO 11737-1:2018/A1 :2021	Sterilization Of Medical Devices Microbiological Methods - Part 1: Determination of A Population of Microorganism on Products.
	EN ISO 11737-2:2020	Sterilization of Medical Devices - Microbiological methods Part 2: Tests of Sterility Performed in The Validation of a Sterilization Process
	ASTM E2315-23	Standard Guide for Assessment of Antimicrobial Activity Using a Time-Kill Procedure
	USP 51	Preservative Effectiveness Test

Title: Product Code Listing and Description: HYDROCYN aqua Gel			
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Product Name and Description

No	Product Name	Brand Family	Product Code	Description
1	HYDROCYN aqua gel	Bactiguard Wound Care	HW40F900	BG WC HYDROCYN aqua gel, tube, 15g
2	HYDROCYN aqua gel	Bactiguard Wound Care	HW41F900	BG WC HYDROCYN aqua gel, tube, 30g
3	HYDROCYN aqua gel	Bactiguard Wound Care	HW42C900	BG WC HYDROCYN aqua gel, tube, 50g
4	HYDROCYN aqua gel	Bactiguard Wound Care	HW4CB900	BG WC HYDROCYN aqua gel, tube, 100g
5	HYDROCYN aqua gel spray	Bactiguard Wound Care	HW42E800	BG WC HYDROCYN aqua gel, spray, 50g
6	HYDROCYN aqua gel spray	Bactiguard Wound Care	HW4CG800	BG WC HYDROCYN aqua gel, spray, 100g