



Title: DECLARATION OF CONFORMITY: HYDROCYN aqua			
Document type: Technical Documentation	Doc Id: VMD-DOC-005-07	Issue Date: 15/12/2023	Page: 1(1)


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EUROPEAN REPRESENTATIVE:	MR.G.ELKAYAM Obelis s.a Bd. General Wahis 53 1030 Brussels Belgium
MEDICAL DEVICE:	Wound Management solution
PRODUCT NAME:	HYDROCYN aqua (refer Product Code Listing)
CLASSIFICATION:	III (Rule 13)
GMDN CODE:	59523
CONFORMITY ASSESSMENT ROUTE:	Annex II (Excluding Section 4) Annex II (Including Section 4)
STANDARD APPLIED:	Refer to the list of Standards (VMD-LS-001)
NOTIFIED BODY:	UDEM (Mutlukent Mahallesi 2073 Sokak No: 10 Umitkoy- CANKAYA, Ankara, Turkey)
IDENTIFICATION NUMBER:	
(EC) CERTIFICATE (S):	M.2017.106.8971
(EC) DESIGN EXAMINATION: CERTIFICATE (S)	M.2017.106.8971-1
START OF CE-MARKING:	03 rd November 2017
VALIDITY OF CERTIFICATE (S):	27 th May 2024
PLACE, DATE OF DECLARATION:	Penang, Malaysia, 03 rd November 2017
<p>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.</p> <div style="display: flex; align-items: center;">   </div> <p>Rohaniza Othman Senior Manager- Quality Assurance and Regulatory Affairs Date: 15/12/2023 Bactiguard (South East Asia) Sdn.Bhd.</p>	

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Product	Classification
HYDROCYN aqua – Wound Management Solution	Class III

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 11 th Edition	Wound Wash
	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 Wash
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.3 & II.4	Manufacturing Quality System

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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

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Category	Document Code	Scope
e) Chemical, Physical and Biological Properties	ASTM E2799-22	Standard Test Method for Testing Disinfectant Efficacy Against Pseudomonas Aeruginosa Biofilm Using the MBEC Assay
	ASTM D1253-14(2021)e1	Standard Test Method for Residual Chlorine in Water
	ASTM D1498-14(2022)e1	Standard Test Method for Oxidation-Reduction Potential of water
	ASTM D1293-18	Standard Test Method for pH of water
	APHA 5310B	TOC (RODI Water)

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

No	Product Name	Brand Family	Product Code	Description
1	HYDROCYN aqua	Bactiguard Wound Care	HW3CE700	BG WC HYDROCYN aqua 100 ml spray mist
2	HYDROCYN aqua	Bactiguard Wound Care	HW34E100	BG WC HYDROCYN aqua 250 ml bottle capclosure with stopper
3	HYDROCYN aqua	Bactiguard Wound Care	HW34E700	BG WC HYDROCYN aqua 250 ml spray mist
4	HYDROCYN aqua	Bactiguard Wound Care	HW35D100	BG WC HYDROCYN aqua 500 ml bottle cap closure with stopper
5	HYDROCYN aqua	Bactiguard Wound Care	HW36D100	BG WC HYDROCYN aqua 1000 ml bottle cap closure with stopper/ without stopper
6	HYDROCYN aqua	Bactiguard Wound Care	HW35C102	BG WC HYDROCYN aqua 500 ml irrigation bag
7	HYDROCYN aqua	Bactiguard Wound Care	HW36C102	BG WC HYDROCYN aqua 1000 ml irrigation bag
8	HYDROCYN aqua	Bactiguard Wound Care	HW3EC102	BG WC HYDROCYN aqua 3000 ml irrigation bag
9	HYDROCYN aqua Gauze	Bactiguard Wound Care	GW3H103	BG WC HYDROCYN aqua Gauze, 10 x10cm, 8-ply