



EC DECLARATION OF CONFORMITY

CE
0297

UID No.: LR/DOC – Class IIa, Rule 5

Product	Sodium Chloride Eye wash Solution 0.9 % w/v
GMDN Code	37207.
Product description	Sodium Chloride Eye wash Solution 0.9% w/v is sterile, single use device is intended for irrigation (washing) of the eyes, including first aid and the removal of harmful substances and dangerous liquids, like alkali or acids, from an eye in an emergency first aid situation. The product is available in size variants of 2ml, 2.5ml, 5ml, 10ml, 15 ml, 20ml, 25ml and 30 ml consisting 0.9% sodium chloride dissolved in water for injection.
Quality Responsibility	Legency Remedies Pvt Ltd., declares under sole responsibility for complying all the quality requirements of the product
Manufacturer:	Legency Remedies Pvt Ltd Kh. No. 132/2 & 133/2, Village Katha, Baddi, Distt. Solan (H.P.), 173205, INDIA. Phone: 09816099295; 09817602007. Email: legency.remedies@rediffmail.com SRN: IN-MF-000010030
E.U. Representative	EUROPECERT Alsstr 97, 41063 Mönchengladbach, Germany. Tel. +49 (0) 2161 990 883 Email: support@europecert.eu SRN: DE-AR-000004974
Application of Council Directive(s)	Medical Device Directive 93/42/EEC as amended by 2007/47/EEC
Classification of the device:	Class IIa device in accordance with Rule 5 of Annex IX of the MDD 93/42/EEC.
Conformity Assessment Route	MDD 93/42/EEC as amended by 2007/47/EEC Annex II, excluding Section 4 Full Quality Assurance
Standards	EN ISO 13485:2016/A11:2021, EN ISO 15223-1:2016, EN ISO 14971:2019/A11:2021, EN ISO 17665-1:2006, EN ISO 11138-3:2009, EN ISO 11607-1:2020, EN ISO 11607-2:2020
Notified Body's Address	DQS Medizinprodukte GmbH August-Schanz-Straße 21 60433 FRANKFURT AM MAIN, Germany Phone : +49 69 95427 300, Fax: 49 69 95427 388 Email : medizinprodukte@dqs-med.de Website : www.dqs-med.de
Notified body number	0297
EC Certificate No. and Validity	Certificate Registration No. : 543376 MR2 Certificate Unique ID: 170765833 Validity: From 2021-05-06 to 2024-05-26
Declaration: Legency Remedies Pvt. Ltd. Declares that Sodium Chloride Eyewash Solution 0.9% w/v meets the requirements of Quality as per IP/EP/BP specifications and also complies with the provisions of the council of Directives 93/42/EEC as amended by 2007/47/EC Directives for Medical devices. This DoC shall be valid till the validity of the CE certificate.	
Signature :	
Name and Position	Mr. Manoj Jain (Director)

Date	01.12.2022	
Place	Baddi	
Doc No: LR-TF-03: Annexure-1	Revision No: 03	Effective date: 01.12.2022