

**EC DECLARATION OF CONFORMITY****UID No.: LR/DOC – Class IIa, Rule 5**

Product	Sodium Chloride Inhalation Solution 0.9% w/v
GMDN Code	44746
Product description	Sodium Chloride Inhalation Solution 0.9% w/v is used in respiratory therapy or for tracheal or lavage. This sterile, single-use device is intended to be used as an accessory to medicinal nonventilatory nebulizers for respiratory therapy or for tracheal inhalation or lavage therapy. Sodium Chloride Inhalation Solution 0.9% w/v. The size variants of the product are 2ml, 2.5ml, 5ml, 10ml, 15 ml, 20ml, 25ml and 30ml and made of 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 that are applicable on this 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 as amended by 2007/47/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, ISO 20417:2021, 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 and	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 Inhalation 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-02: Annexure-1	Revision No: 05	Effective date: 01/12/2022