

EU Quality Assurance Certificate

Regulation (EU) 2017/745, Annex XI Part A

MDR 824791 R000

Manufacturer: Neelkanth Polymer Industries

Address:

Plot No. R-585, TTC Industrial Area
Behind Golden Garage
Rabale, Rabale MIDC
Navi Mumbai
Maharashtra
400 701
India

Single Registration Number: Not available

EU Authorised Representative: SOBEL CONSULTANCY, UNIPESSOAL LDA.

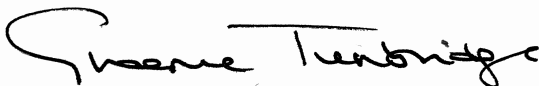
Address:

Rua Julieta Ferrão 12, 6º, Esc. 605
Lisboa
1600-131
Portugal

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/745, Annex XI part A, the quality system meets the requirements of the Regulation. For the placing on the market of Class III and Class IIb devices an additional Annex X certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2026-02-23**

Current Issue Date: **2026-02-23**

Starting Validity Date: **2026-02-23**

Expiry Date: **2031-02-22**

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.
This certificate was issued electronically and is bound by the conditions of the contract.

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Device Schedule: Class IIa, Custom-made and other devices

Device(s)	Risk Classification
Oral Dosing Measuring Syringes	Class Im
Measuring Cups and Spoons	Class Im

For Class Im devices, the Notified Body conformity assessment is limited to the aspects relating to the conformity of the devices with the metrological requirements.



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NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at Seventh and Eighth Floors, The Acre, 90 Long Acre, London, WC2E 9RA, UK.
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Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
Current	30433542	Issued



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