



EC Certificate



Certificate Number: DGM 930

This is to certify that the quality management system of;

NEELKANTH POLYMER INDUSTRIES

Head Office : Plot No. R-585, TTC IND. Area, Rabale Midc,
Navi Mumbai-400701, India

Factory Address : Plot No. R-585, TTC IND. Area, Rabale Midc,
Navi Mumbai-400701, India

For design, production and final product inspections/testing of products:

As per details

Has been assessed with respect to:

**The conformity assessment procedure described in Annex II
excluding section 4 of Council Directive 93/42/EEC on Medical
Devices, as amended**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

This EC certificate is issued in accordance with Presafe Denmark A/S' terms and conditions of Council Directive 93/42/EEC concerning medical devices and entitles the manufacturer to affix the CR mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits in accordance with the Directive.



For Presafe Denmark A/S

Date of issue: 2020-10-07
Expires: 2025-10-06
Initial date of issue: 2020-10-07
Reference: aur2a1503v301f930



Presafe Denmark A/S
Notified Body, Identification No. 0543
Tuborg Parkvej 8, 2900 Hellerup, Denmark
www.presafe.cc/admin





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Product List

NEELKANTH POLYMER INDUSTRIES

The following products are covered by DGM

Jurisdiction

Application of Council Directive 93/24/EEC of 14 June 1993

Product Description

Oral Dispenser - 2ml, 3ml, 5ml, 6ml, 10ml, 12ml, 20ml

Rubber Dropper Assembly, Glass Dropper Assembly, Measuring Cups

Measuring Spoons, Pilfer Proof Caps, Child Resistance Caps (CRC)

Flip Top Caps, Tablet Bottles, Silicon Rubber Teats, Eye Drop Bottles, Dry Syrup Bottles,

Crew Caps, Adopter, Plastic Plug, Piles Applicators, PCO Caps, Baby Droppers Set,

Tablet Applicators, Gel Applicators, Oral Dispenser (0.3ml, 0.5ml, 1ml)

Sites covered by this certificate

Site Name	Address
Neelkanth Polymer Industries	Head Office : Head Office : Plot No. R-585, TTC IND. Area, Rabale Midc, Navi Mumbai-400701, India Factory Address : Plot No. R-585, TTC IND. Area, Rabale Midc, Navi Mumbai-400701, India

"The products on this list have been accepted by Presafe Denmark A/S"

Date: 2020-10-07

Name and signature: Carsten Worin

Title: Jensen



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NEELKANTH POLYMER INDUSTRIES

Terms and conditions

The certificate is subject to the following terms and conditions:

Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive (EU) 2016/425, as amended, concerning liability of defective products.

The certificate is only valid for the products and/or manufacturing premises listed above. The manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.

The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid. Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

Changes in the quality system affecting production.

Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate



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