



CERTIFICATE

EC Certificate No. 1434-MDD-162/2021

Full Quality Assurance System

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the quality assurance system in the organization:

Meghdoot Pharma

**Udyog Mandir No. 1, Office No.3-B, Pitamber Lane, Mahim
West, Mumbai - 400016, India**

for the design, manufacture and final inspection of
medical devices, class III

Povidone Iodine Non-Adherent Wound Dressing

**POVITULLE, MEGHDin, AQVIDINE, POVIGAUZE, DELTAJODINE
(sizes 9.5 cm x 9.5 cm and 5 cm x 5 cm)**

complies with requirements of Annex II (excluding Section 4) to Directive 93/42/EEC (as amended) implemented into
Polish law, as evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 12.04.2021 to 27.05.2024

The date of issue of the Certificate: 12.04.2021



Issued under the Contract No. MD-63/2020
Application No. 077/2020, 070/2021
Certificate bears the qualified signature.
Warsaw, 12.04.2021
Module H2/3/4/5

**Anna
Małgorzata
Wyroba**

Vice-President

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.04.12
11:04:37 +02'00'



CERTIFICATE

EC Certificate No. 1434-MDD-161/2021

EC Design-examination

Directive 93/42/EEC concerning medical devices

Polish Centre for Testing and Certification certifies
that the documentation submitted by:

Meghdoot Pharma

**Udyog Mandir No. 1, Office No.3-B, Pitamber Lane, Mahim
West, Mumbai - 400016, India**

related to the medical device, class III

Povidone Iodine Non-Adherent Wound Dressing

**POVITULLE, MEGHdin, AQVIDINE, POVIGAUZE, DELTAJODINE
(sizes 9.5 cm x 9.5 cm and 5 cm x 5 cm)**

was examined in accordance with Annex II (Section 4) to Directive 93/42/EEC (as amended) implemented into Polish law, as
evidenced by the audit conducted by the PCBC

Validity of the Certificate: from 12.04.2021 to 27.05.2024

The date of issue of the Certificate: 12.04.2021



Issued under the Contract No. MD-63/2020
Application No. 077/2020, 070/2021
Certificate bears the qualified signature.
Warsaw, 12.04.2021
Module H1

**Anna
Małgorzata
Wyroba**

Elektronicznie
podpisany przez Anna
Małgorzata Wyroba
Data: 2021.04.12
11:03:51 +02'00'
Vice-President



Procedo
INTERNATIONAL CERTIFICATION



Quality management system

CERTIFICATE

This is to certify that the Quality management system for medical devices of company

MEGHDOOT PHARMA

Office no. 3-B, Udyog Mandir No.1, Pitamber Lane,
Mahim-West, Mumbai-400016, India

Company's Logo



has been found in compliance with requirements of the standard

EN ISO 13485: 2016

for the following scope:

Design, Manufacture and Sales of Bandages and Wound Dressings

Certificate no.: QMS-13-010-2021

Date of issue: 15/02/2022
Initial certificate issue: 15/02/2022

On condition that organisation will maintain an effective quality management system for medical devices, this certificate remains valid to 14/02/2025.



Ing. Lubica Škrovanová
Head of Certification body



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ICO: 52327230

CE13 v04 10/2021 EN



Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 526052 Defries Industries Pty Ltd - MEGHdin Povidone Iodine non-adherent wound dressing - Dressing, wound-nonadherent, permeable, antimicrobial

ARTG entry for Medical Device Included Class III
Sponsor Defries Industries Pty Ltd
Postal Address PO Box 876, NOBLE PARK, VIC, 3174
Australia
ARTG Start Date 28/04/2026
Product Category Medical Device Class III
Status Active
Approval Area Medical Devices

Conditions

- The inclusion of the kind of device in the ARTG is subject to compliance with all conditions placed or imposed on the ARTG entry. Refer Part 4-5, Division 2 (Conditions) of the Therapeutic Goods Act 1989 and Part 5, Division 5.2 (Conditions) of the Therapeutic Goods (Medical Devices) Regulations 2002 for relevant information.
- Breaching conditions of the inclusion related to the device of the kind may lead to suspension or cancellation of the ARTG entry; may be a criminal offence; and civil penalties may apply.

Manufacturers

Name	Address	Location Id
Meghdoot Pharma	Udyog Mandir No 1 Office No 3-B Pitamber Lane Mahim West, Mumbai, 400016 India	149909

Products

1 . MEGHdin Povidone Iodine non-adherent wound dressing - Dressing, wound-nonadherent, permeable, antimicrobial

Product Type	Single Device Product	Effective Date	28/04/2026
GMDN	47203 Dressing, wound-nonadherent, permeable, antimicrobial		
Functional Description	Povidone Iodine non-adherent wound dressing is a single use device consisting of knitted viscose fabric impregnated with ointment of Povidone Iodine 10% U.S.P. (available Iodine 1%) in inactive ingredient base of polyethylene glycol & purified water. The impregnated dressing is covered between two HDPE films and packed in a glassine- poly aluminum- poly peelable heat sealed pouch.		
Intended Purpose	MEGHdin Povidone Iodine non-adherent wound dressing is designed to protect wounds from infection. It is suitable for superficial skin-loss injuries, minor burns & ulcerative wounds.		
Variant information	Size (cm) 9.5cm x 9.5cm Size (cm) 5cm x 5cm		

Specific Conditions

No Specific Conditions included on Record

Public Summary

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