



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Johnson & Johnson Medical Pty Ltd

for approval to supply

Johnson & Johnson Medical Pty Ltd - Biopatch Protective Disk with CHG - Exudate-absorbent dressing, non-hydrophilic-gel-forming, antimicrobial

ARTG Identifier	452665
ARTG Start Date	18/06/2024
Product Category	Medical Device Included Class III
GMDN	48124
GMDN Term	Exudate-absorbent dressing, non-hydrophilic-gel-forming, antimicrobial
Intended Purpose	For use as a hydrophilic wound dressing that is used to absorb exudate and to cover a wound caused by the use of vascular and non-vascular percutaneous medical devices such as: IV catheters, central venous lines, arterial catheters, dialysis catheters, peripherally inserted coronary catheters, mid-line catheters, drains, chest tubes, externally placed orthopedic pins, and epidural catheters. It is also intended to reduce local infections, catheter-related blood stream infections (CRBSI), and skin colonization of microorganisms commonly related to CRBSI, in patients with central venous or arterial catheters.

Manufacturer Details	Address	Certificate number(s)
Integra Lifesciences Corporation	1100 Campus Road Princeton , New Jersey , 08540 United States Of America	DV-2024-MC-02789-1

ARTG Standard Conditions

The above Medical Device Included Class III has been entered on the Register subject to the following 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.

Products Covered by This Entry

1. Biopatch Protective Disk with CHG - Exudate-absorbent dressing, non-hydrophilic-gel-forming, antimicrobial

Functional Description	It is a hydrophilic polyurethane absorptive foam with Chlorhexidine Gluconate (CHG). The foam material absorbs up to eight times its own weight in fluid, while the CHG incorporated into the dressing inhibits bacterial growth under the dressing.
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Variant Information

Description	Range
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Description	Range
Diameter (cm)	1.9 to 2.5
Opening width (mm)	1.5 to 7

Product Specific Conditions

No specific conditions have been recorded against this entry.

Therapeutic Goods Administration
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