Device Schedule:

Intended Purpose as per the Instructions for Use:

BIOPATCH® containing Chlorhexidine Gluconate is intended 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.

Risk Classification: Class III

Type (Codes as per EU 2017/2185): MDN 1204

Basic UDI-DI: 038178B0024TT8K

Device Name	Model
BioPatch® protective disk with CHG	44150 – 2.5 cm disk with 4.0mm centre hole and printed, blue scrim
BioPatch® protective disk with CHG	44151 – 1.9 cm disk with 1.5mm centre hole and printed, blue scrim
BioPatch® protective disk with CHG	44152 – 2.5 cm disk with 7.0mm centre hole and printed, blue scrim