

Device Schedule:

Intended Purpose as per the Instructions for Use:

The PROLENE™ Hernia System is indicated for the open repair of abdominal wall hernia defects.

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Risk Classification	Basic UDI-DI
PROLENE Hernia System	PROLENE Hernia System	MDN 1104	Class III Implantable	0705031a0119858

Additional Information:

Product Name (as indicated on DoC)	Product Code	Product Description
PROLENE™ Hernia System	PHSE1	PROLENE Hernia System Extended Mesh, 10cm Underlay (Extended Onlay)
	PHSE	PROLENE Hernia System Extended Mesh, 10cm Underlay (Extended Onlay)
	PHSE6	PROLENE Hernia System Extended Mesh, 10cm Underlay (Extended Onlay)
	PHSL	PROLENE Hernia System Large Mesh, 10cm Underlay
	PHSL1	PROLENE Hernia System Large Mesh, 10cm Underlay
	PHSL6	PROLENE Hernia System Large Mesh, 10cm Underlay
	PHSM1	PROLENE Hernia System Medium Mesh, 7.5cm Underlay
	PHSM	PROLENE Hernia System Medium Mesh, 7.5cm Underlay
	PHSM6	PROLENE Hernia System Medium Mesh, 7.5cm Underlay