

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:
15012-2019-CE-IND-NA-PS

Project No.:
PRJC-584412-2018-PRC-IND

Valid Until:
27 May 2024

This is to certify that the quality system of:

Amaryllis Healthcare Pvt. Ltd

#112, Bommasandra Jigani Link Road Industrial Area, Bandenelasandra village Road,
Jigani Hobli, Anekal Taluk. BANGALORE -560105.India

For design, production and final product inspection/testing of:

**STERILE DISPOSABLE SURGICAL GOWNS, SURGICAL
DRAPES AND SURGICAL KITS.**

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.

Place and date:
Høvik, 25 May 2020



For:
DNV GL PRESAFE AS
Notified Body No.: 2460

Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see
www.dnvgl.com/assurance/certificates-in-the-blockchain.html



Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

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Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Original Certificate	25-05-2020

Products covered by this Certificate:

Product Description	Product Name	Class
Sterile Disposable Drape	IPCS10 Caesarean Drape AMARYLLIS	Is
	IPMM10 Maternity Drape AMARYLLIS	
	IPND10 Normal Delivery Drape AMARYLLIS	
	IPND10W Hysteroscopy Drape AMARYLLIS	
	IPAG10 Angiography Drape AMARYLLIS	
	IPFR10 Femoral Radial Drape AMARYLLIS	
	IPFR11 Femoral Drape AMARYLLIS	
	IPRS10 Radial Drape AMARYLLIS	
	IPBA21W Patient Head Drape AMARYLLIS	
	IPED10 Eye Drape AMARYLLIS/ Ophthalmic Drape AMARYLLIS	
	IPBK10 Bilateral Knee O Drape AMARYLLIS Premium	
	IPBL10 Boot leggings AMARYLLIS	
	IPCL10 Cling Drape AMARYLLIS	
	IPSA10 Shoulder Arthroscopy Drape AMARYLLIS	
	IPHO10P Hip O Drape AMARYLLIS	
	IPHU10 Hip U Drape AMARYLLIS	
	IPIS10P Impervious Split Drape AMARYLLIS Premium	
	IPSU10 Split U Drape AMARYLLIS	
	IPKA10 Knee Arthroscopy Drape AMARYLLIS	
	IPKO10 Knee O Drape AMARYLLIS	
	IPLD15 Wing Sheet AMARYLLIS	
	IPLS10 Lamino spinal Drape AMARYLLIS	
	IPAD10 Abdominal Drape AMARYLLIS with 12cm Fenestration	
	IPAD11 Abdominal Drape AMARYLLIS	
	IPAD12 Abdominal Drape AMARYLLIS	
	IPLY10 Laparoscopy Drape AMARYLLIS	
	IPBS26W Patient Bed Drape AMARYLLIS	
	IPDX10P Drape AMARYLLIS X-Large Premium	

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IPPR10 Perineal Drape AMARYLLIS
IPGU10 General U Drape AMARYLLIS
IPHD10 Hole Drape AMARYLLIS
IPHD11 Hole Drape AMARYLLIS -Medium with Adhesive
IPHD12 Hole Drape AMARYLLIS -Large with Adhesive
IPHD15 Hole Drape AMARYLLIS -Small with ABS
IPTS10 Triangle Sheet AMARYLLIS
IPHF10P Half Drape AMARYLLIS Premium
IPSD10 Small Drape AMARYLLIS
IPSD10W Surgery Drape AMARYLLIS Sheet Medium
IPHL10 Drape AMARYLLIS-Leggings
IPLD10 Large Drape AMARYLLIS with Adhesive
IPMD10 Medium Drape AMARYLLIS with Adhesive
IPLD10W Large Drape AMARYLLIS
IPUS10 Underneath Sheet with Abs AMARYLLIS
IPCR10 Craniotomy Drape AMARYLLIS
IPCT10 CVTS Drape AMARYLLIS-Adult
IPCT11 CVTS Drape AMARYLLIS-Pediatric
IPCT12 CVTS Drape AMARYLLIS-Infant
IPGD10 Groin Drape AMARYLLIS
IPPC10 PCNL Drape AMARYLLIS
IPTU10 TURP Drape AMARYLLIS
IPUP15 Under Buttock Drape AMARYLLIS
IPPM10 Pacemaker Drape AMARYLLIS
IPPR10 Perineal Drape AMARYLLIS
IPBA21 Basin Stand Sheet AMARYLLIS
IPBA22 Basin Stand Cover AMARYLLIS
IPCC10 C-Arm Cover Drape AMARYLLIS
IPCC20 C-Arm Cover Drape AMARYLLIS
IPEC20 Camera Cover AMARYLLIS
IPEC21 Camera Cover Mini AMARYLLIS
IPLD 16 Plain Big Sheet AMARYLLIS
IPLT20 Main Trolley Sheet with Abs AMARYLLIS
IPLT20W Trolley Sheet with Abs AMARYLLIS
IPMT20W Large Trolley Sheet with ABS AMARYLLIS
IPMT20 Medium Trolley Sheet with Abs AMARYLLIS
IPLT21 Trolley Sheet AMARYLLIS
IPMT22 Trolley Sheet AMARYLLIS
IPLT25P Back Table Cover Premium AMARYLLIS
IPMC20 Mayo Trolley Cover AMARYLLIS
IPMC21 Mayo Trolley Cover AMARYLLIS

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	IPMC20P Mayo Trolley Cover with ABS AMARYLLIS	
	IPMI20 Microscope Drape AMARYLLIS	
	IPMT21 Trolley Sheet-Medium AMARYLLIS	
	IPOP10 Drape AMARYLLIS OP Tape	
	IPPS23 OT Table Sheet – Small AMARYLLIS	
	IPPS24 OT Table sheet – Large AMARYLLIS	
	IPSI10 Side Drape AMARYLLIS	
	IPSI11 Side Drape AMARYLLIS	
	IPSI15 Utility Drape AMARYLLIS Big size	
	IPSS10 Screen Sheet AMARYLLIS	
Sterile Disposable Gown Size: (S/ M/ L / XL / XXL/ XXXL)	IPRG30 Reinforced Gown AMARYLLIS	Is
	IPSG30 Surgeon Gown AMARYLLIS	
	IPBG30W Surgeon Gown AMARYLLIS (Level 4)	
	IPPG10 Patient Gown AMARYLLIS	
	IPSR30 Scrub Suit Set AMARYLLIS	
	IPSR40 Scrub Suit Pant AMARYLLIS	
	IPSR36 Scrub Suit Shirt AMARYLLIS	
	IPBG30 BVB GOWN AMARYLLIS	
	IPIG30 Isolation Gown AMARYLLIS	
	IPFG30 Cover all full Gown AMARYLLIS	
	IPCG30 Cathlab Gown AMARYLLIS	
Sterile Disposable Kits	AHCTBG10 CVTS OT Pack – Adult AMARYLLIS	Is
	AHCTBG11 Surgical Gown pack AMARYLLIS	
	AHCTBG13 TROLLEY Pack AMARYLLIS	
	AHCTBG20 CVTS OT Pack – Pediatric AMARYLLIS	
	AHCTBG30 CVTS OT Pack – Infant AMARYLLIS	
	AHCTBG12 CVTS Patient pack – Adult AMARYLLIS	
	AHCTBG22 CVTS Patient pack – Pediatric AMARYLLIS	
	AHCTBG32 CVTS Patient pack – Infant AMARYLLIS	
	AHCIAP10 Angioplasty OT Pack AMARYLLIS	
	AHCIPP20 Pacemaker OT Pack AMARYLLIS	
	AHCABG10 CABG Adult Cardiac Pack AMARYLLIS	
	AHCABG12 CABG - Patient Drape AMARYLLIS	
	AHCABG13 CABG - Trolley Drape AMARYLLIS	
	AHCABG20 Pediatric pack AMARYLLIS	
	AHCIAG10 Angiography Kit AMARYLLIS	
	AHORTH12 THR Patient pack AMARYLLIS	
	AHORTH10 THR OT Pack AMARYLLIS	
	AHORTH11 THR Gown Pack AMARYLLIS	
	AHORTH13 THR Trolley Pack AMARYLLIS	
	AHORTK10 TKR OT Pack AMARYLLIS	

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AHORTK11 TKR Gown Pack AMARYLLIS
AHORTK12 TKR Patient Pack AMARYLLIS
AHORTK13 TKR Trolley Pack AMARYLLIS
AHORKA10 Knee Arthroscopy OT Pack AMARYLLIS
AHORKA11 Knee Arthroscopy Gown Pack AMARYLLIS
AHORKA12 Knee Arthroscopy Patient Pack AMARYLLIS
AHORKA13 Knee Arthroscopy Trolley Pack AMARYLLIS
AHORSA10 Shoulder Arthroscopy OT Pack AMARYLLIS
AHORSA11 Shoulder Arthroscopy Gown Pack AMARYLLIS
AHORSA12 Shoulder Arthroscopy Patient Pack AMARYLLIS
AHORSA13 Shoulder Arthroscopy Trolley Pack AMARYLLIS
AHORMJ10 Ortho Major OT Pack AMARYLLIS
AHORMJ11 Ortho Major Gown Pack AMARYLLIS
AHORMJ12 Ortho Major Patient Pack AMARYLLIS
AHORMJ13 Ortho Major Trolley Pack AMARYLLIS
AHOPOK10 Ophthalmic Kit AMARYLLIS
AHHYPG10 Patient Gown Kit AMARYLLIS
AHORMN10 Ortho Minor OT Pack AMARYLLIS
AHORMN11 Ortho Minor Gown Pack AMARYLLIS
AHORMN12 Ortho Minor Patient Pack AMARYLLIS
AHORMN13 Ortho Minor Trolley Pack AMARYLLIS
AHORLS10 Lamino Spinal OT Pack AMARYLLIS
AHORLS11 Lamino Spinal Gown Pack AMARYLLIS
AHORLS12 Lamino Spinal Patient Pack AMARYLLIS
AHORLS13 Lamino spinal Trolley pack AMARYLLIS
AHGYND10 Normal Delivery OT pack AMARYLLIS
AHGYCS10 LSCS OT Pack AMARYLLIS
AHGYHS10 Hysteroscopy OT pack AMARYLLIS
AHSGKR10 Kidney Transplant Recipient OT Pack AMARYLLIS
AHSGKR11 Surgeon Gown Pack AMARYLLIS
AHGYAH10 Abdominal Hysterectomy OT pack AMARYLLIS
AHGYVH10 Vaginal Hysterectomy OT pack AMARYLLIS
AHGYIF10 IVF OT Pack AMARYLLIS
AHGYDC10 D&C OT Pack AMARYLLIS
AHSKS11 Safety kit – Standard AMARYLLIS
AHSKI12 Safety kit – Intra AMARYLLIS
AHSKU13 Safety kit – Ultra AMARYLLIS
AHСКА14 Safety kit – Advanced AMARYLLIS
AHSKR10 Safety OT kit – Regular AMARYLLIS
AHNENO10 Neuro OT Pack AMARYLLIS
AHNENO11 Neuro Gown pack AMARYLLIS

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AHNENO12 Neuro patient Pack AMARYLLIS
AHNENO13 Neuro Trolley pack AMARYLLIS
AHNECR10 Craniotomy OT Pack AMARYLLIS
AHNECR11 Craniotomy Gown pack AMARYLLIS
AHNECR12 Craniotomy patient pack AMARYLLIS
AHURPC10 PCNL OT Pack AMARYLLIS
AHURTU10 TURP OT Pack AMARYLLIS
AHSGKD10 Kidney Transplant Donor OT Pack AMARYLLIS
AHSGKD11 Surgeon Gown AMARYLLIS
AHSGKD12 Patient Drape Kit AMARYLLIS
AHSGKD13 Basin Stand Cover AMARYLLIS
AHSGKD14 Thomas Refractor Kit AMARYLLIS
AHSGKD15 Trolley Drape Kit AMARYLLIS
AHSGKD16 Perfusion Kit AMARYLLIS
AHSGKR12 Patient Drape Kit AMARYLLIS
AHSGKR13 Basin Stand Cover AMARYLLIS
AHSGKR14 Thomas Refractor Kit AMARYLLIS
AHSGKR15 Trolley Drape Kit AMARYLLIS
AHSGGE10 General Surgery Minor OT Pack AMARYLLIS
AHSGGE20 General Surgery Major OT Pack AMARYLLIS
AHGSLP10 Laparoscopy OT Pack AMARYLLIS
AHGSLP11 Laparoscopy Pack AMARYLLIS
AHGSPS11 Plastic Surgery (Major) AMARYLLIS
AHGSPS10 Plastic Surgery (Minor) AMARYLLIS
AHGSUP10 Universal Pack AMARYLLIS
AHETEN10 ENT Pack AMARYLLIS
AHGSIU10 CU/CVP Line Kit AMARYLLIS
AHSGLD10 Liver Transplant Donor OT Pack AMARYLLIS
AHSGLD11 Surgeon Gown Kit AMARYLLIS
AHSGLD12 Patient Drape Kit AMARYLLIS
AHSGLD13 Thomas Refractor Kit & Perfusion kit AMARYLLIS
AHSGLD14 Trolley Drape Kit AMARYLLIS
AHSGLR10 Liver Transplant Recipient OT Pack AMARYLLIS
AHSGLR11 Surgeon Gown Kit AMARYLLIS
AHSGLR12 Patient Drape Kit AMARYLLIS
AHSGLR13 Basin Stand Cover AMARYLLIS
AHSGLR14 Thomas Refractor Kit AMARYLLIS
AHSGLR15 Trolley Drape Kit AMARYLLIS

The complete list of devices is filed with the Notified Body

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Sites covered by this certificate

Site Name	Address
Amaryllis Healthcare Pvt.Ltd	#112, Bommasandra Jigani Link Road Industrial Area, Bandenelasandra village Road, Jigani Hobli, Anekal Taluk. BANGALORE -560105.India

EU Representative

Amstermed BV, Boslaan 39 2132 RJ Hoofddorp The Netherlands Phone: +3123565637
email: infor@amstermed.nl

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 85/374/EEC, 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