

www.angimed.it tel. 085.975035 fax 085.9960203 info@angimed.it

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TRADING NAME	HAPPY COVER® RIG
DESCRIPTION	Polyethylene vomit bag, for an easy and safe seal of its opened upper side, after use. Inside the bag there is a superabsorbent molecule-powder named SGAIEL® that transforms liquids into solids. This powder is enclosed in a water-soluble film which acts in contact with liquids. Ready for use.
TEM CODE	AM003
RDM (Italy)	1570463
CND (Italy)	A060399
PACKAGING	pcs 20
DIMENSIONS	mm. 250x250
EXPIRING TIME	5 years
BELONGING CLASS OF MD	Classe I medical device - Not sterile Pursuant to 93/42/EEC
CE MARK	Pursuant to 93/42/EEC and 2007/47 EEC of 09/02/2007
INTENDED USE	Disposable vomit system for use in public and private hospitals, first aid, Emergency and transport companies
RAW MATERIALS	Polyethylene HDPE. White cross-linked sodium polyacrylate enclosed in a water-soluble film.



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INSTRUCTIONS FOR USE	Happy Cover® RIG is not used in combination with other device. SGAIEL® powder turns vomit into a gelatinous substance in about one minute. After use close the bag by adhesive liner or make a knot. Dispose as per current legislation.
CAUTION	Do not use sharp objects to open the package Do not disperse in the environment after use. Do not use if package is open or damaged.
CONTRAINDICATIONS	No contraindications by using these medical devices.
STORAGE	Store in a cool, dry place away from heat sources and sunlight.
TRANSPORTATION	Not regulated by EEC and Italia Transport Department as dangerous product. Terrestrial transport (RID/ADR): not dangerous. Maritime transport (IMG): not dangerous. Airplane transport (ICAD/IATA): not dangerous.
APPLICABLE REGULATION	93/42/EEC of 06/14/1993 2007/47 EEC of 09/05/2007
GMDN	Code GMDN: 3923.21 Description: Polyethylene sick bag with a folding and internal double-sided adhesive pocket that allows an easy and safe sealing of its open upper side after use. Its interior is covered with a molecule-powder named "SGAIEL®" with an absorbing function that turns liquids into solids. This powder is enclosed in a water-soluble film which acts upon contact with liquid. Ready for use.
<u>Įm</u>	Angimed S.r.l. Corso Umberto I, 590 ed.66 - 65015 Montesilvano (PE)



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DECLARATION OF CONFORMITY CE APPLICATIONS WITH DIRECTIVES 93/42 / EEC OF 14 JUNE 1993 - 2007/47 / EC OF SEPT EMBER 5, 2007

Alessandro Di Teodoro, as the legal representative of Angimed S.r.l., declare

that medical devices class I below identified, meet the Essential Requirements of the Directive 93/42/EC of 14 June 1993 and 2007/47/EC of September 5, 2007 and are used for their intended use. This statement is based on the technical documentation referenced in the Procedure of Conformity Annex VII.

	ANGIMED SRL - MANUFACTURING PLANT:		
Cor	Corso Umberto I, 590 / ED.66 - 65015 Montesilvano (PE) Italy		
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CODE	PRODUCT DESCRIPTION		
AM001N	BEDPAN COVER		
AM001	BEDPAN COVER		
AM002	P.PURINE SYSTEM		
AM002HM	P.PURINE SYSTEM WHIT LANYARD		
AM003	RIG -VOMIT SYSTEM		
AM003HM	RIG -VOMIT SYSTEM WHITH LANYARD		
AM004	SGAIEL- POWDER SUPER ABSORBENT 400GR.		
AM005	SGAIEL- POWDER SUPER ABSORBENT 200GR.		
AM006	SGAIEL- POWDER SUPER ABSORBENT 1000GR.		
AM007	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 05 GR.		
AM008	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 10 GR.		
AM009	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 15 GR.		
AM013	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 13 GR.		
AM020	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 20 GR.		
AM025	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 25 GR.		
AM050	SGAIEL- POWDER SUPER ABSORBENT WITH IDRO-SOLUBLE FILM - 50 GR.		

Alessandro Di Teodoro (C.E.O.)

