

4560-164 Guilhufe, Penafiel - Portugal

Ref: 488-139

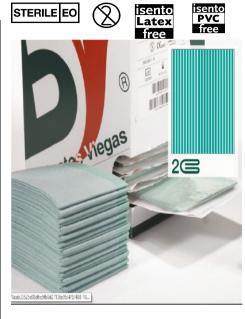
Product Specification

Brand:



DRQ 14/21 REV.00 2020/09/08

Final dimensions:	50 cm x60 cm x 2 plv	
Composition:	Polyethylene film, Viscose nonwoven.	
Size variation:	±10 %	
Latex:	Free	
PVC:	Free	
Re use:	No	
Sterilized by:	Ethylene Oxide	
Shelf life:	60 months	
CFU/g	N.A.	
Cleanliness- Microbial	N.A. CFU/100cm^2	
Class.EN 13795-1:2019	HIGH PERFORMANCE	
Resist Micro.Penetra.Wet	6,0 IB	
Clean particulate matter	<3,5 IPM	
Linting	<4.0 log10lint count	
Resist. liq. penetration	>100 cmH2O	
Dry Bursting Strength	>40 kPa	
Wet bursting strength	>40 kPa	
Dry Tensile strength MD	>50 N/5cm	
Dry Tensile strength TD	>20 N/5 cm	
Wet Tensile strength MD	>40 N/5cm	
Wet Tensile strength TD	>20 N/5cm	



Nr and Revision Date:	9 2020/09/07	
CE Class:	I Steril	
CE mark:	CE1639	
Compliance with:	MDD 93/42/EEC amended by 2007/47/EC	
	EN_ISO_11737-2.2009; ISO_11135.2014; EN_ISO_11607-2.2017; ASTM_F1980_16;	EN_ISO_13485.2016_AC18; EN 556-1.2001_AC.2006; EN_ISO_11607_1 2017; ISO_10993-1.2018; EN_ISO_14971.2012; EN_ISO_15223-1.2016;
Applicable norms:	EN_1041.2008_A1.2013 ;	

Level		Туре	Dimension	Stamp	Labels
1	1	Flexible peel-open pack	134x200mm		
2	60	Folding box	216x151x308mm		labeled
3	600	Carton box	780x225x635mm		labeled

Important Notes:	The device is intended to be used on a single patient during one single procedure to prevent risks from contamination, including possible infections, and/or functional damage.
Storage instructions	Store in a dry place at room temperature and protect from sunlight. The product has a good stability and therefore, normal conditions of medical devices storage shall apply
Waste instructions	No special requirements. The waste must be disposed according to local legal regulations for the disposable of medical waste.
Intended use	Intended to be used for sterile draping of patients and equipment in operating room, to prevent transfer of infective agents.

Non-harmonized symbols used in article labeling	plies	
Environment - Packaging waste	Weight (gr) of packing material used in 100 pcs	771

ISSUED BY: Quality Management Department, 2020/12/17