

SKINTACT® ECG Electrode F-50

Code: 58016



PRODUCT	
Characteristics	disposable, pregelled, non sterile
Shelf Life	24 months unopened pouch
Storing Conditions (min./max.)	+5°C/+30°C
X-Ray Translucent	No
MR Conditional 1.5T / 3.0T	No

DIMENSIONS	
Electrode Size - max L/W [cm]	Ø 5.0
Total Area [cm ²]	appr. 19.6
Gel Area [cm ²]	appr. 2.8
Adhesive Area (Backing Material) [cm ²]	appr. 15.8

CLASSIFICATION AND STANDARDS		
EU	Classification (MDD Art.9)	Class I
USA	Classification (CFR 21 870.2360)	Class II
Canada	Classification (SOR/98-282)	Class II
China	Classification (Order No. 15 of CFDA)	Class II

MATERIALS	
Stud	Stainless Steel
Label	PET-Foil
Backing Material	PE-Foam
Adhesive	Medical-Grade Acrylate
Sensor	Ag/AgCl coated ABS
Sponge	PUR-Foam
Gel	Aqua-Wet (Liquid Gel)
Release Liner	Siliconized PET-Foil (transparent)

MATERIALS PACKAGING	
Pouch	Polyethylene-Aluminium-Paper
Box	Cardboard

STANDARD PACKAGING	
Pieces/Card	1
Pieces/Pouch	30
Pieces/Box	1200
Lot number and expiration date on every pouch and box.	

DIMENSIONS PACKAGING	
Box (L/W/H) [cm]	38.5/28.5/21.0

ENVIRONMENTAL INFORMATION	
Compliance with RoHS Directive	Yes
Compliance with REACH Regulation	Yes
PVC free*	Yes
Phthalate free*	Yes
Not made with natural rubber latex	Yes

BIOCOMPATIBILITY	Result
ISO 10993-1 ff.	Pass

REACH CANDIDATE LIST SUBSTANCES	
Information according to Art. 33 for substances contained above 0.1 wt%	
Substance	n.a.

*According to valid regulations ≤ 0.1 wt% or no intentionally added content

ELECTRICAL VALUES	Units	AAMI Limits	Result
DC-Offset	[mV]	≤ 100	pass
DC-Offset (5 sec after Capacitor Discharge)	[mV]	≤ 100	pass
Recovery Slope	[mV/sec]	± 1	pass
AC-Impedance with 10 Hertz	[Ω]	≤ 2000	pass
Internal Noise Test	[µV]	≤ 150	pass
Bias-Tolerance	[mV]	≤ 100	pass