

**NIKOTABS ECG Diagnostic Electrode #0315**



PRODUCT	
<i>Recomm. Application</i>	Diagnostic Resting
<i>Characteristics</i>	disposable, pregelled, no latex, no PVC, non sterile
<i>Shelf Life</i>	36 months unopened pouch
<i>Storing Conditions (min. / max.)</i>	+5° C / +30° C
<i>X-Ray Translucent</i>	yes

DIMENSIONS	
<i>Electrode Shape</i>	rectangular
<i>Electrode Size - max L/W [cm]</i>	3.4 / 2.1
<i>Total Area [cm<sup>2</sup>]</i>	appr. 7.14
<i>Gel Area [cm<sup>2</sup>]</i>	appr. 5.10
<i>Adhesive Area [cm<sup>2</sup>]</i>	appr. 5.10
<i>Conductive Area [cm<sup>2</sup>]</i>	appr. 5.10

CLASSIFICATION AND STANDARDS	
<i>Classification (MDR Annex VIII)</i>	Class I
<i>Classification (21CFR 870.2360.)</i>	Class II

MATERIALS	
<i>Label</i>	PET-Foil
<i>Backing Material:</i>	PET/Paper (Carbon coated)
<i>Adhesive</i>	Solid Adhesive Gel
<i>Sensor</i>	Ag / AgCl coating
<i>Gel</i>	Aqua-Tac (Solid Adhesive Gel)
<i>Release Liner</i>	Siliconized Paper (PE coated)

MATERIALS PACKAGING	
<i>Pouches, Inner Layer</i>	Polyethylene (PE)
<i>Pouches, Centre Layer</i>	Aluminium (Al)
<i>Pouches, Outer Layer</i>	Paper
<i>Boxes</i>	Cardboard

STANDARD PACKAGING	
<i>Pieces / Card</i>	10
<i>Pieces / Pouch</i>	100
<i>Pieces / Box</i>	500
<i>Pieces/ Case</i>	5000

Lot number and expiration date on every pouch and box

DIMENSIONS PACKAGING	
<i>Box (L/W/H) [cm]</i>	18/ 9/ 10
<i>Case (L/W/H) [cm]</i>	23/ 18/ 20

BIOCOMPATIBILITY		
<i>Test - ISO 10993-1</i>	<i>Backing Material (Adhesive)</i>	<i>Gel</i>
<i>Cytotoxicity</i>	pass	pass
<i>Skin Irritation</i>	pass	pass
<i>Sensitization</i>	pass	pass

ELECTRICAL VALUES	Units	Typical Values	AAMI Limits
<i>DC-Offset</i>	[mV]	≤ 1.0	≤ 100
<i>DC-Offset (5 sec after Capacitor Discharge)</i>	[mV]	≤ 15	≤ 100
<i>Recovery Slope</i>	[mV/sec]	≤ -0,3	± 1
<i>AC-Impedance with 10 Hertz</i>	[Ω]	≤ 600	≤ 2000
<i>Internal Noise Test</i>	[μV]	≤ 10	≤ 150
<i>Bias-Tolerance (over 24 h)</i>	[mV]	≤ 10	≤100 (over 8 h)