

Keywords

Product groups Health care / medical devices

Testing fields Mechanics

Technical details

TEST ITEM	TESTED PROPERTY	TESTING METHOD
Breast Implant	Tests for shell integrity: Elongation	ABNT NBR ISO 14607:2013 – ANEXO B
		ISO 37:2017
	Tests for shell integrity: Tensile set	ABNT NBR ISO 14607:2013 – ANEXO B
		ISO 37:2017
	Tests for shell integrity: Determination of tear strength	ABNT NBR ISO 14607:2013 – ANEXO B
		ISO 34-1:2015
	Tests for shell integrity: Determination of tensile stress-strain properties	ABNT NBR ISO 14607:2013 – ANEXO B
		ISO 37:2017
	Gel Cohesion Testing	ABNT NBR ISO 14607:2013 – ANEXO D
	Fatigue Testing	ABNT NBR ISO 14607:2013 – ANEXO E
	Static Burst Testing	ABNT NBR ISO 14607:2013 – ANEXO E
	Packaging Inspection	ABNT NBR ISO 14607:2013
		ISO 14630:2012, Seção 10
		Portaria Inmetro nº 162, de 05/04/2012 – Anexo B.
	Test Purity: Particle Contamination by Optical Microscopy	ABNT NBR ISO 14949:2011

Aims of the PT scheme	
Target group of participants	Brazilian laboratories that can perform tests in Breast Implant
Linked to specific legislation / standards	RDC da ANVISA nº 16, de 21 de março de 2012 Portaria Inmetro nº 162, de 05/04/2012 ISO 13485:2016 ISO 14607:2013 ISO 14949:2011