



Title	Declaration of Conformity	Revision	Page
		5	1 of 1
		Date	29/08/2017

Declaration of Conformity

PRODUCT IDENTIFICATION	
Product name	Model/number
Test ELISA Chagas III	192 Determinations Code 1300442

MANUFACTURER		
Name of company	Address	Representative
GrupoBios S.A.	Av Zanartu 1482 Santiago 778-0272 Chile	Cetna Skorin M.

AUTHORIZED REPRESENTATIVE		
Name of company	Address	Telephone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague, Netherlands	+31.70.345.8570 - phone +31.70.346.7299 - fax service@emergogroup.com

CONFORMITY ASSESSMENT	
Device classification	Route to compliance
Other IVD – Self declaration	Annex III of IVDD 98/79/EC Council Directive

GrupoBios S.A. declares that the above mentioned products meet the provision of the Council Directive 98/79/EC for In vitro Diagnostics.

COMPANY REPRESENTATIVE: Cetna Skorin M.

TITLE: General Manager **SIGNATURE:**

DATE: European Format 01/04/2018

GrupoBios S.A.