

Declaration of Conformity

PRODUCT IDENTIFICATION

Product name	Model/number
Gold Hpdry	50 Determinations Code GH 230391 (Polish version) Code GH 230391(English version)

MANUFACTURER

Name of company	Address	Representative
GrupoBios S.A.	Alonso de Córdova 5320, piso 2 Las Condes 7561275 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 Europe@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 20/12/2022



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