EU DECLARATION OF CONFORMITY

Manufacturer:	HGH Medical Group GmbH August Jakschstrasse 85 9020 Klagenfurt - Austria
European Authorized Representative:	HGH Medical Group GmbH HGH Medical Group GmbH
Product Name:	Monkeypox Antigen Rapid Test Cassette
Specification:	IMPV-c112, IMPV-8112
Classification:	Other device not listed under Annex II and self-testing of Directive 98/79/EC
Conformity assessment route:	Annex III,except Point 6,of Directive 98/79/EC
Applicable Standards:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 23640:2015, EN ISO 13612:2002, EN ISO 17511:2003, EN 13975:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016, EN 13641:2002

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

Klagenfurt May 22, 2022

Place,date

Herbert Angst e.U. General Manager

Legally binding signature, Position