



Declaration of Conformity

MANUFACTURER	Green Cross Medical Science Corporation 26, Mugeuk-ro 65beon-gil, Geumwang-eup, Eumseong-gun, Chungcheongbuk-do, 27632, REPUBLIC OF KOREA
EUROPEAN REPRESENTATIVE	MT Promedt Consulting GmbH Altenhofstrasse 80, 66386 St. Ingbert, Germany
EMDA CODE,	15 04 80 90 00 Others Viral Antigen/Antibody Detection
PRODUCT NAME/ REF NO.	GENEDIA W COVID-19 Ag / 643G
CLASSIFICATION	Others IVD / Non List A, Non List B and not for self-testing
CONFORMITY ASSESSMENT	Directive 98/79/EC on IVDD, ANNEX III

WE HEREBY DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 98/79/EC FOR IN VITRO DIAGNOSTIC MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED	EN ISO 13485:2016, ISO 14971:2019, EN13612:2002, EN ISO 23640:2015, EN 13641:2002, EN ISO 17511:2003, EN ISO 18113-1:2011, EN ISO 18113-2:2011, EN ISO 15223-1:2016
------------------------------	---

PLACE, DATE OF ISSUE	Chungcheongbuk-do, Republic of Korea, 2020.08.25
-----------------------------	--

SIGNATURE

Jong-Kwan, Ko
QMR (Quality Management Representative)