

# CERTIFICATE OF IVD REGISTRATION

THIS IS TO CERTIFY THAT, ACCORDING TO THE COUNCIL DIRECTIVE 98/79/EC, CARETECHION GmbH PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

**NAME:** 3D BIOMEDICINE SCIENCE & TECHNOLOGY CO., LIMITED  
**ADDRESS:** BLOCK A, BUILDING 2, NO.158 XINJUNHUAN ROAD, PUJIANG TOWN, MINHANG DISTRICT, SHANGHAI, CHINA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

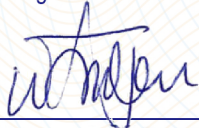
The manufacturer has declared that the IVD devices comply with the Directive including all essential requirements.

The manufacturer has provided Caretechion GmbH with all the appropriate declarations according to the 98/79/EC Directive-article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC.

The notification of the following In-Vitro Diagnostics medical devices has been completed by Caretechion GmbH on the 23/03/2020 in compliance with the European Council Directive 98/79/EC -article 10 requirements. This product had been approved by Germany competent authority on May 19, 2020.

Registration Number	Commercial Name	GMDN Code	GMDN Descriptor	Valid from
DE/CA20/IVD-Caretechion-04/20	ANDiS SARS-CoV-2 and Influenza A/B RT-qPCR Detection Kit	64747	SARS-CoV-2 nucleic acid IVD kit, nucleic acid technique (NAT)	23/03/2020
DE/CA20/IVD-Caretechion-03/20	Automated Nucleic Acids Extraction System	60736	Nucleic acid sample preparation instrument IVD automated	20/03/2020
DE/CA20/IVD-Caretechion-02/20	ANDiS Viral RNA Auto Extraction & Purification Kit	52521	Nucleic acid extraction /isolation kit IVD	20/02/2020

As long as the manufacturer will continue complying with the here above mentioned requirements\* he therefore:  
-Is required to affix the CE marking on these devices;  
-Place these devices in the Territory of Germany and/or the other EEA Member States  
(excluding territories not in alignment with Decision 2010/227/EU).



Caretechion GmbH

Amtsgericht Düsseldorf 40002 Düsseldorf

Caretechion GmbH  
Niederrheinstr.71  
4047 Düsseldorf,  
Germany

