Declaration of Conformity

YD Diagnostics

Manufacturer	**YD Diagnostics CORP.** SRN: KR-MF-000023981 Address: 76, Seori-ro, Idong-eup, Cheoin-gu, Yongin-si, Gyeonggi-do, 17127, Republic of Korea

We are issuing the Declaration of Conformity under our sole responsibility.
We declare that the medical device.

Product (Number, Name)	M9	URiSCAN PRO
Basic UDI-DI	88061256M9D5	
Notify Body	© TÜV SÜD PRODUCT SERVICE GMBH (NB ID: 0123) Ridlerstrasse 65, 80339 ,München, Germany	
Identification of the certificate: **(Valid until)**	Q5 049752 0033 Rev.00 (from 2021-07-01 until 2024-06-30) TUV100 01 1037(from 2020-04-30 until 2023-04-29)	
EMDN Code **Nomenclature term**	W02010701 Urinalysis(UR)-Laboratory analysers-Instruments	
Risk Classification	IVD for Professional Use (Not listed in the Annex II, IVD 98/79/EC)	

We here with 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 and manufacturer is exclusively responsible for the declaration of conformity.

Conformity is also given to the following EU regulation(s):Directive 2011/65/EU(RoHS)

EU regulation and CS applied to the product are as follows:

Conformity is also given to the following EU regulation(s):
DIRECTIVE 98/79/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL Directive 2011/65/EU

Applied Common Specification (S):	
EN ISO 13485:2016, ISO 13485:2016	ISO 9001:2015
EN ISO 14971:2012, ISO 14971:2019	TR/ISO 24917:2020
IEC 62366-1:2015, IEC 62366:2007, EN 62366:2018, EN 62366-4:2015	EN 61010-1:2010 +A1:2019 +AC:2019 EN 61010-2+101:2017
EN 61326-1:2013, EN 61326-2-6:2013	ISO 15223-1:2016, EN ISO 15223-1:2016
ISO 18113-1:2009, EN ISO 18113-1: 2011	ISO 18113-3: 2009, EN ISO 18113-3: 2011

European Representative	**CARE diagnostica Laborreagenzien GmbH** Weseler Str. 110, 46562 Voerde, Germany

Signed for on behalf of

Yongin-si, Gyeonggi-do, Republic of Korea
2022.12.08

City, date

Signature **C.E.O / H. Y. Lee**

Rev.08/2022-12-08