

# Declaration of Conformity

**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)**

M7

URiSCAN Optima

**Basic UDI-DI**

88061256M7CZ

**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**

W02010701

**Nomenclature term**

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 62366-4:2015EN 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**