

EU Declaration of Conformity

Manufacturer name/Actor ID/SRN: **3DHISTECH Kft. (HU-MF-000014337)**
Manufacturer address: **H-1141 Budapest, Öv Street 3.**
Product name: **PANNORAMIC 480 DX Digital Scanner**
Basic UDI-DI code: **599957147036S5 / GS1**
Risk class: **Class A**

Intended use: The scanner is a digital slide microscope that automatically creates a digital image of the inserted glass slides. The digital microscope can be part of the diagnostic Pathology Management System, it uses barcode-based slide recognition and communication to identify the slides (with the CaseManager DX report inventory system).

The Pathology Management System is intended to be used to analyze and evaluate pathological specimens, and this product assists the pathologist in reviewing and interpreting digital images of a surgical pathology (histology) study that includes PANNORAMIC® 480 DX Digital Scanner. Digital slides can be displayed, reviewed and analyzed using the slide viewer and image analysis module of CaseManager DX.

It is the responsibility of a qualified pathologist to employ appropriate procedures and safeguards to assure the validity of the interpretation of images obtained using the system.

I hereby declare on my own responsibility that the above-mentioned product has been submitted to a performance assessment and fulfils the essential requirements of the following Regulation (EU) 2017/746 of the European Parliament and of the Council and draw up the technical documentation of product. Under normal and proper conditions of use, the operation of the device is not harmful to the patient's, operator's, or other personnel's health or safety.

Quality Management System: **EN ISO 13485:2016**

Name and address of the Certification Body: **SGS United Kingdom Ltd, Unit 202B Worle Parkway, Weston Super Mare, Somerset BS22 6WA, United Kingdom**

GMDN code: **62575**

The conformity of products in the following regulations, directives and harmonized standards assured:

Regulation (EU) 2017/746;

RoHS Directives 2011/65/EU; 2014/30/EU; 2014/35/EU;

EN 61326-2-6:2013: Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

EN 61010-1:2010: Safety requirements for electrical equipment for measurement, control, and laboratory use. Part 1: General requirements (IEC 61010-1:2010)

EN 61010-2-081:2015: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-081: Particular requirements for automatic and semi-automatic laboratory equipment for analysis and other purposes

EN 61010-2-101:2017: Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment.

We undertake to develop and maintain Quality Management System with which after-production feedbacks on the device will be monitored and supervised, and corrective steps will be initiated if necessary.

We undertake to immediately report any erroneous operation, deterioration of characteristics or performance of the product, as well as any insufficiency in the labeling or the content of the user's manual that may cause or may have caused either death, injury, or serious health problems to the patient or to the operator of the device. All technical documentation will be handed over for further examination to the National Institute of Pharmacy and Nutrition authority upon request.

The product expected lifespan is 7 years.

This EU Declaration of Conformity issued for this product, are valid for every 3DHISTECH Kft. products on which the CE mark is indicated and is produced in accordance with the Regulation (EU) 2017/746.

In the event of unauthorized modification of the device listed below, this declaration becomes invalid.

Place and date of issue: Budapest, 9th March, 2023.

17.
3DHISTECH KFT.
1141. Budapest, Öv u. 3.
Adószám: 10620386-2-42
Bszsz.: 11744034-20020660


Bela Molnar, Ph.D., D.Sc.
CEO
3DHISTECH Kft.