NUCLEIX

Company Confidential	
Document Name :Bladder EpiCheck Declaration of Conformity	
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Approvals :

Job Title	Approved by	Quality Role	Date	Signature status	Comment
President EMEA	Eli Frydman	Reviewer and Approver	18-May-2022	Approved	

Change Revision History :

Rev.	Chg. #	Date	Change Description	ECO	Release Date
D	1	18-May-2022	Update Authorized Representative under ECO-29598	ECO-29598	18-May-2022
C	1	09-May-2022	Update the DOC including: • Clarify product group • Add extended indication • Clairify responsibility Original signed outside of Orcanos	ECO-28814	11-May-2022
B	1	09-May-2022	Upload for traceability - signed outside the system Updated due to expiration of previous DOC		
A	1	26-May-2020	CE-01-02 Nucleix Declaration of Conformity Bladder EpiCheck Valid due to 31-Dec-2020		

EC Declaration of Conformity

According to Annex III of IVDD 98/79/EC

Manufacturer:

Nucleix Ltd.
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We, Nucleix Ltd., manufacturers of IVD Systems for detection and monitoring of bladder cancer and upper tract urothelial carcinoma, that are placed in the European market, declare under our exclusive responsibility, that our products conform and meet the essential requirements set out in Annex I and the conformity assessment procedure set out in Annex III of the in-vitro Diagnostics Medical Device Directive 98/79/EC.

Product Group: Bladder EpiCheck Kit
(Catalogue Number: NX899090, not a saleable device)

Products:

Product Name	Catalogue Number
Bladder EpiCheck DNA Extraction Kit	NX-899090-01C
Bladder EpiCheck Test Kit	NX-899090-02C
Bladder EpiCheck Software	NX-899090-03C

Classification: Self Declaration

Intended Use:

The Bladder EpiCheck test is an in vitro diagnostic device for the detection of DNA methylation patterns in urine that are associated with urothelial carcinoma. It is intended for use as a noninvasive method for monitoring of tumor recurrence in conjunction with standard diagnostic procedures in patients previously diagnosed with bladder cancer and/or upper tract urothelial carcinoma.

Additionally, Bladder EpiCheck is intended for use as an aid in the detection of bladder cancer and upper tract urothelial carcinoma, in patients presenting with hematuria and/or other urinary tract symptoms and/or findings with a suspicion of malignancy, in conjunction with standard diagnostic procedures.

Authorized Representative:

Qarad EC-REP BV,
Pas 257
2440 Geel
Belgium

We hereby approve Qarad EC-REP BV to act as our Authorized Representative in the European Community

Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by the authorized representative in Europe.

Signature:

Name: Eli Frydman

Title: President EMEA

Signature: Eli Frydman

Eli Frydman Ph.D MBA
President - EMEA
NUCLEIX Ltd

Place and Date: Rehovot, Israel
May 18, 2022