



EC DECLARATION OF CONFORMITY
According to Annex III of the IVD Directive 98/79/EC

Tosoh Corporation
Shiba-Koen First Bldg., 3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan

Certifies that following IVD products:

ST AIA-PACK D-Dimer	Cat No. 0025232
ST AIA-PACK D-Dimer CALIBRATOR SET	Cat No. 0025332
ST AIA-PACK D-Dimer SAMPLE DILUTING SOLUTION	Cat No. 0025532
AIA-PACK D-Dimer CONTROL SET	Cat No. 0025432

are manufactured by Tosoh Corporation.

These products:

1. Comply with all Essential Requirements (Annex I) of the IVD Directive 98/79/EC.
2. This compliance has been properly documented using a checklist created from Annex I of the IVD Directive 98/79/EC, linked to all supporting Technical Documentation. This documentation includes both product specific and process (quality management system) specific documents.
3. TOSOH Corporation has its quality management system in place based on ISO 9001: 2008, ISO 13485: 2003 and EN ISO 13485: 2012/AC: 2012.
4. These certificates have been issued by TÜV Rheinland.
5. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

Shiba-Koen First Bldg.
3-8-2, Shiba, Minato-ku
Tokyo 105-8623, Japan

April 8, 2013


Hitoshi Tashiro
Quality Assurance Manager
Bioscience Division
Tosoh Corporation

(Place and date issued)

(Name and signature as well as position of declarant)



EC DECLARATION OF CONFORMITY
According to Annex III of the IVD Directive 98/79/EC

Tosoh Corporation
Shiba-Koen First Bldg., 3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan

Certifies that following IVD products:

ST AIA-PACK cTnl 3rd-Gen	Cat No. 0025215
ST AIA-PACK cTnl 3rd-Gen CALIBRATOR SET	Cat No. 0025315
ST AIA-PACK cTnl 3rd-Gen SAMPLE DILUTING SOLUTION	Cat No. 0025515

are manufactured by Tosoh Corporation.

These products:

1. Comply with all Essential Requirements (Annex I) of the IVD Directive 98/79/EC.
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3. Tosoh Corporation has its quality management system in place based on ISO 9001: 2008, ISO 13485: 2003 and EN ISO 13485: 2012/AC: 2012.
4. These certificates have been issued by TÜV Rheinland.
5. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

Shiba-Koen First Bldg.
3-8-2, Shiba, Minato-ku
Tokyo 105-8623, Japan

March 31, 2014


Hitoshi Tashiro
Quality Assurance Manager
Bioscience Division
Tosoh Corporation

(Place and date issued)

(Name and signature as well as position of declarant)



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Tosoh Corporation
Shiba-Koen First Bldg., 3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan

Certifies that the following IVD products:

ST AIA-PACK BNP	Cat No. 0025228
ST AIA-PACK BNP CALIBRATOR SET	Cat No. 0025328
ST AIA-PACK BNP SAMPLE DILUTING SOLUTION	Cat No. 0025528

are manufactured by Tosoh Corporation.

These products:

1. Comply with all Essential Requirements (Annex I) of the IVD Directive 98/79/EC.
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3. Tosoh Corporation has its quality management system in place based on ISO 9001: 2008, ISO 13485: 2003 and EN ISO 13485: 2012, EN ISO 13485: 2012 + AC: 2012.
4. These certificates have been issued by TÜV Rheinland.
5. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

Shiba-Koen First Bldg.
3-8-2, Shiba, Minato-ku
Tokyo 105-8623, Japan

June 22, 2016


Hitoshi Tashiro
Quality Assurance Manager
Bioscience Division
Tosoh Corporation



EC DECLARATION OF CONFORMITY
According to Annex III of the IVD Directive 98/79/EC

Tosoh Corporation
Shiba-Koen First Bldg., 3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan

Certifies that the following IVD products:

AIA-PACK BNP CONTROL SET

Cat No. 0025428

are manufactured by Tosoh Corporation.

These products:

1. Comply with all Essential Requirements (Annex I) of the IVD Directive 98/79/EC.
2. This compliance has been properly documented using a checklist created from Annex I of the IVD Directive 98/79/EC, linked to all supporting Technical Documentation. This documentation includes both product specific and process (quality management system) specific documents.
3. Tosoh Corporation has its quality management system in place based on ISO 9001: 2008, ISO 13485: 2003 and EN ISO 13485: 2012, EN ISO 13485: 2012 + AC: 2012.
4. These certificates have been issued by TÜV Rheinland.
5. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

Shiba-Koen First Bldg.
3-8-2, Shiba, Minato-ku
Tokyo 105-8623, Japan

March 18, 2016


Hitoshi Tashiro
Quality Assurance Manager
Bioscience Division
Tosoh Corporation

(Place and date issued)

(Name and signature as well as position of declarant)



EC DECLARATION OF CONFORMITY

According to Annex III of the IVD Directive 98/79/EC

Tosoh Corporation
Shiba-Koen First Bldg., 3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan

Certifies that the following IVD products:

ST AIA-PACK TSH	Cat No. 0025294
AIA-PACK TSH 3rd-Gen CALIBRATOR SET	Cat No. 0020394
AIA-PACK TSH 3rd-Gen SAMPLE DILUTING SOLUTION	Cat No. 0020594

are manufactured by Tosoh Corporation.

These products:

1. Comply with all Essential Requirements (Annex I) of the IVD Directive 98/79/EC.
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3. TOSOH Corporation has its quality management system in place based on ISO9001: 2008, ISO 13485: 2003 and EN ISO 13485: 2012/AC: 2012.
4. These certificates have been issued by TÜV Rheinland.
5. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

Shiba-Koen First Bldg.
3-8-2, Shiba, Minato-ku
Tokyo 105-8623, Japan

April 8, 2013


Hitoshi Tashiro
Quality Assurance Manager
Bioscience Division
Tosoh Corporation

(Place and date issued)

(Name and signature as well as position of declarant)



EC DECLARATION OF CONFORMITY

According to Annex III of the IVD Directive 98/79/EC

Tosoh Corporation
Shiba-Koen First Bldg., 3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan

Certifies that the following IVD products:

AIA-PACK FT4	Cat No. 0020268
ST AIA-PACK FT4	Cat No. 0025268
AIA-PACK FT4 CALIBRATOR SET	Cat No. 0020368

are manufactured by TOSOH Corporation.

These products:

1. Comply with all Essential Requirements (Annex I) of the IVD Directive 98/79/EC.
2. This compliance has been properly documented using a checklist created from Annex I of the IVD Directive 98/79/EC, linked to all supporting Technical Documentation. This documentation includes both product specific and process (quality management system) specific documents.
3. TOSOH Corporation has its quality management system in place based on ISO 9001: 2008, ISO 13485: 2003 and EN ISO 13485: 2012/AC: 2012.
4. These certificates have been issued by TÜV Rheinland.
5. This Declaration of Conformity is signed below, certifying these requirements have been met and documented.

Shiba-Koen First Bldg.
3-8-2, Shiba, Minato-ku
Tokyo 105-8623, Japan

March 15, 2013


Hitoshi Tashiro
Quality Assurance Manager
Bioscience Division
Tosoh Corporation

(Place and date issued)

(Name and signature as well as position of declarant)



TOSOH EUROPE N.V.

Company Name	Tosoh Europe N.V
Address	Transportstraat 4, Tessenderlo, 3980, Belgium

EU Declaration of Conformity

Issued by..... **Tosoh Europe N.V.**
Registered Company Address..... Transportstraat 4
Tessenderlo, 3980
Belgium

The above manufacturer declares under its sole responsibility that the product listed below:

Brand Name..... Tosoh
Product name..... AIA-PACK MULTI ANALYTE CONTROL
Product description..... Quality Control
Classification..... Annex II, List B
Conformity route..... Annex IV, Full Quality Assurance System – Notified Body 0197
Intended Use..... The AIA-PACK MULTI ANALYTE CONTROL is intended for in vitro diagnostic use only for performing quality control procedures, by healthcare professionals, with the Tosoh Automated Immunoassay Analyzers for the analytes listed in the EXTRA INFO AIA-PACK MULTI ANALYTE CONTROL.

The product herewith complies with the essential requirements of the following applicable European directives:

The In Vitro Diagnostic Medical Devices Directive 98/79/EC

Complies with all applicable directives as demonstrated by conformance to the following harmonized standards:

QMS EN ISO 13485:2016
Risk Management EN ISO 14971:2012
Labelling EN 15223-1:2016
EN ISO 18113-2:2011
Stability EN ISO 23640:2015
Performance Evaluation EN ISO 20776-1:2006

And therefore complies with the essential requirements of those directives.

Signed for and on behalf of..... Tosoh Europe N.V.
Place and date of issue..... Tessenderlo, 28-Aug-2019
Name and function..... Ioannis Bekatoros, Senior Regulatory Affairs Officer

Signature.....

TOSOH EUROPE N.V.
Transportstraat 4
B-3980 Tessenderlo, Belgium
Tel.: +32 (0) 13 66 88 30
Fax: +32 (0) 13 67 37 90
BTW 0425 952 041

Tosoh Europe N.V./S.A., Transportstraat 4, Industrieterrein Ravenshout 5353, 3980 Tessenderlo, Belgium

Tel: +32 (0)13 66 88 30 – Fax: +32 (0)13 66 47 49

www.tosohbioscience.com



APPENDIX

The preceding declaration covers the following product:

Legal Manufacturer	Device reference	Description
Tosoh Europe N.V.	0960474	AIA-PACK MULTI ANALYTE CONTROL



EU DECLARATION OF CONFORMITY

According to Annex IV of the IVD Regulation (EU) 2017/746

Manufacturer	Tosoh Corporation
SRN	JP-MF-000024143
Address	3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan
Authorised Representative	Tosoh Europe N. V.
Address	Transportstraat 4, B-3980 Tessenderlo, Belgium

This EU declaration of conformity is issued under the sole responsibility of Tosoh Corporation.

Basic UDI-DI	456018921000006277
Product Name	AIA-PACK SUBSTRATE SET II
Cat No.	0020968
Class	A

This device is in conformity with the Regulation (EU) 2017/746 and other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

3-8-2, Shiba, Minato-ku
Tokyo 105-8623, Japan

2022-05-26

Yutaka Tahara
Quality Assurance Manager
Bioscience Division
Tosoh Corporation



Declaration of Conformity

This is to certify that following In-Vitro Diagnostic Medical Devices:

Product name	Product code	Basic UDI-DI
AIA-PACK WASH CONCENTRATE	0020955	5430000495000020955MW

are manufactured and sold by:

Tosoh Europe NV
Transportstraat 4, Tessenderlo
Single Registration Number: BE-MF-000000210

These products:

1. Are classified as Class A devices per Rule 5a of Annex VIII of the In-Vitro Diagnostic Medical Device Regulation 2017/746 as amended.
2. Are in conformity with the In Vitro Diagnostic Medical Device Regulation 2017/746 as amended.
3. Comply with the relevant general safety and performance requirements set out in Annex I of the In Vitro Diagnostic Medical Device Regulation 2017/746 as amended.
4. Are manufactured in facilities having a Full Quality System in place based on ISO 13485: 2016. This certificate has been issued by TÜV Rheinland.

This compliance has been documented using a checklist created from Annex I of the European In Vitro Diagnostic Medical Device Regulation, linked to all supporting Technical Documentation set out in Annexes II and III of this Regulation. This documentation includes both product specific and process (Quality System) specific documents.

- This Declaration is issued under the sole responsibility of Tosoh Europe NV.
- This Declaration is issued by Tosoh Europe NV and has unlimited time validity.
- This Declaration is signed below, certifying these requirements have been met and documented.


TOSOH EUROPE N.V.
Transportstraat 4
B-3980 Tessenderlo, Belgium
Tel.: +32 (0) 13 66 88 30
Fax: +32 (0) 13 67 37 90
BTW 0425 952 041

Ioannis Bekatoros

Senior Quality Assurance & Regulatory Affairs Manager

Thursday, May 19, 2022



Declaration of Conformity

This is to certify that following In-Vitro Diagnostic Medical Devices:

Product name	Product code	Basic UDI-DI
AIA-PACK DILUENT CONCENTRATE	0020956	5430000495000020956MY

are manufactured and sold by:

Tosoh Europe NV
Transportstraat 4, Tessenderlo
Single Registration Number: BE-MF-000000210

These products:

1. Are classified as Class A devices per Rule 5a of Annex VIII of the In-Vitro Diagnostic Medical Device Regulation 2017/746 as amended.
2. Are in conformity with the In Vitro Diagnostic Medical Device Regulation 2017/746 as amended.
3. Comply with the relevant general safety and performance requirements set out in Annex I of the In Vitro Diagnostic Medical Device Regulation 2017/746 as amended.
4. Are manufactured in facilities having a Full Quality System in place based on ISO 13485: 2016. This certificate has been issued by TÜV Rheinland.

This compliance has been documented using a checklist created from Annex I of the European In Vitro Diagnostic Medical Device Regulation, linked to all supporting Technical Documentation set out in Annexes II and III of this Regulation. This documentation includes both product specific and process (Quality System) specific documents.

- This Declaration is issued under the sole responsibility of Tosoh Europe NV.
- This Declaration is issued by Tosoh Europe NV and has unlimited time validity.
- This Declaration is signed below, certifying these requirements have been met and documented.



TOSOH EUROPE N.V.
Transportstraat 4
B-3980 Tessenderlo, Belgium
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Fax: +32 (0) 13 67 37 90
BTW 0425 952 041

Ioannis Bekatoros

Senior Quality Assurance & Regulatory Affairs Manager

Thursday, May 19, 2022



EU DECLARATION OF CONFORMITY

According to Annex IV of the IVD Regulation (EU) 2017/746

Manufacturer	Tosoh Corporation
SRN	JP-MF-000024143
Address	3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan
Authorised Representative	Tosoh Europe N. V.
Address	Transportstraat 4, B-3980 Tessenderlo, Belgium

This EU declaration of conformity is issued under the sole responsibility of Tosoh Corporation.

Basic UDI-DI	456018921000006073
Product Name	AIA-PACK DETECTOR STANDARDIZATION TEST CUP
Cat No.	0020970
Class	A

This device is in conformity with the Regulation (EU) 2017/746 and other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

3-8-2, Shiba, Minato-ku
Tokyo 105-8623, Japan

2022-05-26

Yutaka Tahara
Quality Assurance Manager
Bioscience Division
Tosoh Corporation





EU DECLARATION OF CONFORMITY

According to Annex IV of the IVD Regulation (EU) 2017/746

Manufacturer	Tosoh Corporation
SRN	JP-MF-000024143
Address	3-8-2, Shiba, Minato-ku, Tokyo 105-8623, Japan
Authorised Representative	Tosoh Europe N. V.
Address	Transportstraat 4, B-3980 Tessenderlo, Belgium

This EU declaration of conformity is issued under the sole responsibility of Tosoh Corporation.

Basic UDI-DI	456018921000006175
Product Name	AIA-PACK SAMPLE TREATMENT CUP
Cat No.	0020971
Class	A

This device is in conformity with the Regulation (EU) 2017/746 and other relevant Union legislation that provides for the issuing of an EU declaration of conformity.

3-8-2, Shiba, Minato-ku
Tokyo 105-8623, Japan

2022-05-26

Yutaka Tahara
Quality Assurance Manager
Bioscience Division
Tosoh Corporation



To Whom it May Concern

We, TOSOH EUROPE N.V., hereby declare that the following products are consumables to Tosoh HPLC HLC-723x series analyzers and are not In Vitro Diagnostic Devices, as they do not meet the pertinent definition as stipulated in Directive 98/79/EC and the IVD Regulation (EU) 2017/746:

021098 PTFE TIP
R019215L CARBON TIP RACK (023306)
018552L AIA 21 SAMPLE TIPS
0021600 FILTER ELEMENT G8
018581L Cups sample Hitachi vials 2mL
0930007 Sample cups Hitachi type (500pc)
0023861 Flange type filter element (G11)
0023862L Printer Paper (10 pcs) G11

A Declaration of Conformity cannot be issued for these products as they are not IVD and cannot, therefore, be CE marked according to Directive 98/79/EC and the IVD Regulation (EU) 2017/746. While the products are not CE marked, they are manufactured in a controlled area and are subject to regular quality inspections within a statistical process control.


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BTW 0425 952 041

Ioannis Bekatoros
Senior Quality Assurance & Regulatory Affairs Manager
16-SEP-2022