



浙江东方基因生物制品有限公司
Zhejiang Orient Gene Biotech Co., LTD



CE-DOC-OG053-1
Version 1.0

EC Declaration of Conformity

In accordance with Directive 98/79/EC

Legal Manufacturer: *Zhejiang Orient Gene Biotech Co., Ltd*

Legal Manufacturer Address: *3787#, East Yangguang Avenue, Dipu Street,
Anji 313300, Huzhou, Zhejiang, China*

Declares, that the products
Product Name and Model(s)

See attachment

Classification: *Other*

Conformity assessment route: *Annex III (EC DECLARATION OF CONFORMITY)*

We, the Manufacturer, herewith declare with sole responsibility that our product/s mentioned above meet/s the provisions of the Directive 98/79/EC of the European Parliament and of the Council on In-Vitro Diagnostic Medical Devices.

We hereby explicitly appoint

EC Representative's Name: Shanghai International Holding Corp. GmbH (Europe)

EC Representative's Address: Eiffestrasse 80, 20537 Hamburg, Germany

to act as our European Authorized Representative as defined in the aforementioned Directive.

I, the undersigned, hereby declare that the medical devices specified above conform with the directive 98/79/EC on in vitro diagnostic medical devices and pertinent essential requirements

Date Signed: October 13th, 2020

Name of authorized signatory: Joyce Pang

Position held in the company: Vice-President



浙江东方基因生物制品有限公司
Zhejiang Orient Gene Biotech Co., LTD

Attachment to CE-DOC-OG053-1 Version 1.0

Urinalysis Strips	URS-1T
Urinalysis Strips	URS-2T
Urinalysis Strips	URS-3T
Urinalysis Strips	URS-4T
Urinalysis Strips	URS-5T
Urinalysis Strips	URS-6T
Urinalysis Strips	URS-7T
Urinalysis Strips	URS-8T
Urinalysis Strips	URS-9T
Urinalysis Strips	URS-10T
Urinalysis Strips	URS-11T
Urinalysis Strips	URS-12T
Urinalysis Strips	URS-13T
Urinalysis Strips	URS-14T



Manufacturer's Declaration

in relation to Regulation (EU) 2024/1860 amending Regulation (EU) 2017/746 (IVDR) as regards the transitional provisions for certain *in vitro* diagnostic medical devices, in particular with respect to

- the extended transitional periods for devices for which the conformity assessment procedure pursuant to Directive 98/79/EC (IVDD) did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to Regulation (EU) 2017/746 (IVDR) requires the involvement of a notified body *and/or*
- the validity of certificates issued under Directive 98/79/EC (IVDD) (Directive Certificate) *and/or*
- the compliance of the devices and us, as their manufacturer, with the conditions for the continued placing on the market and putting into service

Manufacturer name	Zhejiang Orient Gene Biotech Co.,Ltd
Manufacturer address and contact details	3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China Tel: +86-572-5226111 Fax: +86-572-5226222 Website: www.orientgene.com
Single Registration Number (SRN) (if available)	CN-MF-000017965

Authorised Representative name (if applicable)	Shanghai International Holding Corp. GmbH (Europe)
Authorised Representative address and contact details	Eiffestrasse 80, 20537 Hamburg, Germany
Single Registration Number (SRN) (if available)	DE-AR-000000001

Notified body name (if applicable)	<input checked="" type="checkbox"/> See attached schedule <input type="checkbox"/> Not applicable
Notified body number (if applicable)	<input checked="" type="checkbox"/> See attached schedule <input type="checkbox"/> Not applicable
Directive Certificate number(s) to which this confirmation is made (if applicable)	<input checked="" type="checkbox"/> See attached schedule <input type="checkbox"/> Not applicable



Original expiry date as indicated on the Directive Certificate(s) prior to the extension of the validity (if applicable)	<input checked="" type="checkbox"/> See attached schedule <input type="checkbox"/> Not applicable
End date of extended validity/transition period	<input checked="" type="checkbox"/> See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the **device(s)** listed in the attached schedule the conditions for the legal extension of transitional periods as required in Article 110.3b of the IVDR are met *and/or*
- for the **Directive Certificate(s)** listed in the attached schedule the conditions for the legal extension of validity as required in Article 110.2 of the IVDR are met *and/or*
- the **device(s)** listed in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 110.3c of the IVDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➤ **Devices which were self-declared under the IVDD and require notified body involvement under the IVDR**

In case of devices for which the conformity assessment procedure pursuant to IVDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2022 and for which the conformity assessment procedure pursuant to IVDR requires the involvement of a notified body:

Choose applicable statement:

☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 May 2025 for class D devices

☐ 26 May 2026 for class C devices

☒ 27 May 2027 for class B and class A (sterile) devices

☒ Signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the device(s) listed in the attached schedule or its/their substitutes no later than:

☐ 26 September 2025 for class D devices

☐ 26 September 2026 for class C devices

☒ 27 September 2027 for class B and class A (sterile) devices

☐ We do not intend to lodge an application for conformity for the device as indicated on the attached schedule.



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➤ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the device(s) listed in the attached schedule was/were issued after 25 May 2017, was/were valid on 26 May 2022 and has/have not been withdrawn afterwards.

Choose applicable statements:

☐ Original expiry date *before 9 July 2024*:

☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII IVDR for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of its/their substitute(s), or

☐ Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 54(1) IVDR (may be provided upon request), or

☐ Competent Authority has required us as the manufacturer, in accordance with Article 92(1) IVDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

Choose one of the following statements only if a derogation per Article 54(1) or a requirement per Article 92(1) has been granted by a Competent Authority:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

☐ We do not intend to lodge an application for conformity assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

☐ Original expiry date *after 9 July 2024*:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII IVDR for conformity assessment has/have been lodged or will be lodged by us to a notified body no later than 26 May 2025 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII IVDR before 26 September 2025.

☐ We do not intend to lodge an application for conformity assessment by 26 May 2025 for the devices as indicated on the attached schedule, therefore the transition period will end on 26 May 2025.

☐ assessment by 26 May 2025, therefore the transition period will end on 26 May 2025.

➤ **Quality Management System (QMS)**

Choose one applicable statement:

☐ QMS in accordance with Article 10(8) IVDR will be put in place by no later than 26 May 2025.



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- ☒ QMS in accordance with Article 10(8) IVDR is in place.
☐ Notified body has issued the attached certificate for the IVDR-compliant QMS.

➤ **Device(s) listed in the attached schedule (apart from the device indicated to be withdrawn)**

- The device(s) continue(s) to comply with the IVDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Zhejiang Orient Gene Biotech Co.,Ltd

Location & Date: 3787#, East Yangguang Avenue, Dipu Street, Anji 313300, Huzhou, Zhejiang, China

Signature, Print Name, Title: Joyce Pang, V.P Quality

Contact Details (at least email): joyce.pang@orientgene.com



Zhejiang Orient Gene Biotech Co., Ltd

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s) ¹ (e.g., device name, family/group name, device model or catalogue number)	End date of extended validity / transition period	Substitute Device(s) (if applicable)	Directive Certificate number to which this declaration is issued (if applicable)	Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	Notified Body name and number that issued the Directive Certificate (if applicable)	Notified Body name and number where the IVDR application was lodged/contract signed (if applicable)
Device name: Urinalysis Strips REF: URS-XXT	2029.12.31	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

¹ for devices with IVDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above