EXIMBANK

BANCA COMERCIALĂ "EXIMBANK" S.A.
SUCURSALA Nr. 20
9/1/2025
S20/551
Nr. de ieșire

Digitally signed by Anghel Gabriela-Cristina
Date: 2025.09.02 17:40:05 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

Beneficiar: Centrul Pentru Achiziții Publice Centralizate în Sănătate

Oficiul Băncii: **BC „EXIMBANK" SA, sucursala nr. 20,**
mun. Chişinău, bd. Ştefan cel Mare şi Sfânt 171/1

Data emiterii: 01.09.2025

GARANȚIE DE OFERTĂ Nr. 10802/7

Stimați Domni,

B.C. "Eximbank" S.A., număr de identificare de stat – cod fiscal 1002600010273, adresa: MD2004, Republica Moldova, mun. Chişinău, bd. Ştefan cel Mare şi Sfânt, 171/1, numit în continuare Garant, a fost informată că **„Medist Grup" SRL** (numit în continuare „Ordonator") urmează să înainteze oferta către Dvs. la data de **03.09.2025** (numită în continuare „ofertă") **în scopul atribuirii contractelor subsecvente ca urmare a acordului cadru nr. ocds...23328 din 18.10.2024 încheiat prin procedura de achiziție publică nr. ocds-b3wdp1-MD-1720528223328 din 09.07.2024 privind încheierea acordului-cadru – Achiziționarea dispozitivelor medicale conform Programului Național de combatere a hepatitelor virale B, C, și D pentru anii 2025 - 2027 ,** conform **LP nr. ocds-b3wdp1-MD-1755088100108** din 13.08.2025.

La cererea Ordonatorului, noi, B.C. "Eximbank" S.A., ne asumăm un angajament de plată față de **Centrul Pentru Achiziții Publice Centralizate în Sănătate,** numit în continuare Beneficiar, în sumă sau sume ce nu depăşesc în total suma de **142 712-18 (o sută patruzeci și două mii șapte sute doisprezece) lei 18 bani**.

Angajamentul Garantului este valabil în una din următoarele situații:

a) dacă după expirarea termenului de depunere a ofertei, Ordonatorul își retrage sau își modifică cererea;
b) fiind anunţat de către autoritatea contractantă, în perioada de valabilitate a ofertei, despre adjudecarea contractului: (i) eşuează sau refuză să semneze formularul contractului; sau (ii) eşuează sau refuză să prezinte garanţia de bună execuţie, dacă se cere conform condiţiilor procedurii de achiziţie, ori nu a executat vreo condiţie specificată în documentele de atribuire, înainte de semnarea contractului de achiziţie.

Garantul își asumă angajamentul de a plăti Beneficiarului în limita sumei menționate mai sus, după primirea cererii de plată în scris a Beneficiarului garanției, fără prezentarea documentelor doveditoare, cu condiția menționării în cererea de plată a faptului realizării a uneia sau mai multor situații din cele expuse mai sus.

Orice plată efectuată pe această garanție, va avea ca efect reducerea proporțională a angajamentului Garantului.

Această garanţie va expira în cazul în care ofertantul devine ofertant câştigător, la primirea de către noi a copiei înştiinţării privind adjudecarea contractului, în urma emiterii Garanţiei de bună execuţie eliberată către Dvs. la solicitarea Ordonatorului.

Prezenta garanție intra in vigoare la data **03.09.2025** este valabilă până la data de **31.10.2025** și expiră în totalitate în mod automat în cazul în care cererea Dvs. de plată scrisă, nu ne parvin până la această dată inclusiv, indiferent dacă prezenta Garanție ne este restituită sau nu.

Toate litigiile apărute pe parcursul realizării prezentei garanții, se soluționează în conformitate cu legislația în vigoare a Republicii Moldova.

Cu respect,

Galina Mezleacova
Director Sucursala nr. 20

Digitally signed by Merzleacova Galina
Date: 2025.09.01 10:41:38 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

DECLARAŢIE
privind valabilitatea ofertei

Către: **CENTRUL PENTRU ACHIZITII PUBLICE CENTRALIZATE IN SANATATE**

Stimaţi domni,

Ne angajăm să menținem oferta valabilă, **În scopul atribuirii contractelor subsecvente ca urmare a acordului cadru nr. ocds...23328 din 18.10.2024 încheiat prin procedura de achiziție publică nr. ocds-b3wdp1-MD-1720528223328 din 09.07.2024 privind încheierea acordului-cadru - Achiziționarea dispozitivelor medicale conform Programului Național de combaterea hepatitelor virale B, C și D pentru anii 2025-2027,** pentru o durată de ***30 (treizeci) zile***, respectiv până la data de ***31/10/2025 (ziua/luna/anul),*** și ea va rămâne obligatorie pentru noi și poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 02.09.2025

Cu stimă,
Ofertant/candidat
Gabriela-Cristina Anghel
(semnătura autorizată)

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

DECLARAŢIE
privind neîncadrarea în situaţiile prevăzute la art. 19 din Legea nr.131/2015 privind achiziţiile publice

Subsemnata Gabriela Anghel, în calitate de ofertant la procedura nr. ocds-b3wdp1-MD-1755088100108, privind ***achiziția În scopul atribuirii contractelor subsecvente ca urmare a acordului cadru nr. ocds...23328 din 18.10.2024 încheiat prin procedura de achiziție publică nr. ocds-b3wdp1-MD-1720528223328 din 09.07.2024 privind încheierea acordului-cadru - Achiziționarea dispozitivelor medicale conform Programului Național de combaterea hepatitelor virale B, C și D pentru anii 2025-2027***, declar pe proprie răspundere că:

- Medist Grup SRL, nu se află în niciuna din situațiile de excludere menționate la art.19.

În cazul în care situaţia se va modifica, vom informa imediat autoritatea contractantă.

Gabriela-Cristina Anghel

Medist Grup SRL
02.09.2025

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chișinău, Rep. Moldova
Tel./Fax: +373 22 84 94 95
E-mail: office@medist.md
Web: www.medist.md

IDNO: 1018600004516
TVA: 0508191
BC Victoriabank SA, Filiala nr. 26 Chișinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

WHO list of Prequalified In Vitro Diagnostic Products

Product Name | Manufacturer Name | IVD Category

cepheid | - Any - | Apply

Displaying: 1 - 9 of 9

Download list as CSV file

Product name	Product Code	WHO Product ID	Assay Format	Regulatory Version	Manufacturer name	Pathogen/Disease/Marker	Year prequalification
Xpert HCV Viral Load with GeneXpert Dx, GeneXpert Infinity-48s, and GeneXpert Infinity-80	GXHCV-VL-CE-10	0260-070-00	NAT (nucleic acid testing)	Directive 98/79/EC: Product design examination certificate, Annex IV.4	Cepheid AB	HCV	2017
Xpert HCV VL Fingerstick	GXHCV-FS-CE-10	0453-070-00	NAT (nucleic acid testing)	Directive 98/79/EC: Product design examination certificate, Annex IV.4	Cepheid AB	HCV	2022
Xpert HIV-1 Qual XC	GXHIV-QA-XC-CE-10	0652-070-00	NAT (nucleic acid testing)	Directive 98/79/EC: Product design examination certificate, Annex IV.4	Cepheid AB	HIV	2024
Xpert HIV-1 Quant with GeneXpert Instrument Systems (GeneXpert Infinity-48)	GXHIV-VL-CE-10	0193-070-00	NAT (nucleic acid testing)	Directive 98/79/EC: Product design examination certificate, Annex IV.4	Cepheid AB	HIV	2017
Xpert HIV-1 Quant with GeneXpert Instrument Systems (GeneXpert Infinity-48s)	GXHIV-VL-CE-10	0194-070-00	NAT (nucleic acid testing)	Directive 98/79/EC: Product design examination certificate, Annex IV.4	Cepheid AB	HIV	2017
Xpert HIV-1 Quant with GeneXpert Instrument Systems (GeneXpert Infinity-80)	GXHIV-VL-CE-10	0195-070-00	NAT (nucleic acid testing)	Directive 98/79/EC: Product design examination certificate, Annex IV.4	Cepheid AB	HIV	2017
Xpert HIV-1 Viral Load XC	GXHIV-VL-XC-CE-10	0691-070-00	NAT - qPCR	Directive 98/79/EC: Product design examination certificate, Annex IV.4	Cepheid AB	HIV	2024
Xpert HPV	GXHPV-CE-10	0268-070-00	NAT (nucleic acid testing)	Directive 98/79/EC: Product design examination certificate, Annex IV.4	Cepheid AB	HPV	2017
Xpert MTB/RIF Ultra	GXMTB-ULTRA-HB-10 GXMTB-ULTRA-HB-50	10295-070-00	NAT (nucleic acid testing)	Rest-of-World	Cepheid AB	Mycobacterium tuberculosis complex (MTBC)	2024

EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 744859 R000

Manufacturer: Cepheid AB

Address:
Röntgenvägen 5
SE-171 54 Solna
Sweden

Single Registration Number: SE-MF-000002020

Scope: See attached **Device Schedule**

On the basis of our examination of the quality system in accordance with Regulation (EU) 2017/746, Annex IX Chapter I and III, the quality system meets the requirements of the Regulation. For the placing on the market of Class D devices, and self-test, near-patient test and companion diagnostic devices an Annex IX Chapter II certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2024-03-29**

Current Issue Date: **2024-08-06**

Starting Validity Date: **2024-08-06**

Expiry Date: **2029-03-28**

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EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 744859 R000

Device Schedule: Class D, C and B devices

Class D devices	**Intended purpose**
Xpert® HBV Viral Load	See IVDR 745676
Xpert® HCV Viral Load	See IVDR 745679
Xpert® HIV-1 Viral Load XC	See IVDR 745674
Class D near-patient test devices	**Intended purpose**
Xpert® HIV-1 Qual XC	See IVDR 745677
Xpert® HCV VL Fingerstick	See IVDR 745675
Class C devices near-patient test devices	**Intended purpose**
Xpert® MTB/RIF Ultra (NPT)	See IVDR 744865
Xpert® CT/NG (NPT)	See IVDR 745360
Xpert® Xpress GBS	See IVDR 793827
Class C devices	**Intended purpose**
W0105 – Infectious Immunology IVP 3011 - In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS)	Nucleic Acid devices intended to be used for detection of infectious agents, including sexually transmitted diseases, and screening of cervical cancer.
Class B devices	**Intended purpose**
IVR0503 - Devices intended to be used to determine the presence of, or exposure to an infectious agent including sexually transmitted agents.	Nucleic acid devices intended to be used for qualitative detection and/or identification of infectious agents

First Issue Date: **2024-03-29**

Current Issue Date: **2024-08-06**

Starting Validity Date: **2024-08-06**

Expiry Date: **2029-03-28**

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EU Quality Management System Certificate

Regulation (EU) 2017/746, Annex IX Chapter I and III

IVDR 744859 R000

Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from Certificate.Verification@bsigroup.com)

Date	Reference Number	Action
2024-03-29	3390342	Issued
Current	30204517	Supplemented – addition/certification of Class B device categories IVR 0503 Supplemented – addition/certification of 3 Class C NPT devices (IVR 0503): 1. Xpert® MTB/RIF Ultra 2. Xpert® CT/NG 3. Xpert® Xpress GBS Supplemented – addition of further devices to generic device group Class C W0105 + IVP 3011.

First Issue Date: **2024-03-29**

Current Issue Date: **2024-08-06**

Starting Validity Date: **2024-08-06**

Expiry Date: **2029-03-28**

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EC Design-Examination Certificate

Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex IV Section 4

No. **CE 708526**

Issued To: **Cepheid AB**
Röntgenvägen 5
SE-171 54 Solna
Sweden

In respect of:

Xpert HBV Viral Load

on the basis of our examination of the design dossier relating to the device under the requirements of Council Directive 98/79/EC, Annex IV Section 4, the design of the device conforms to the requirements of 98/79/EC.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Graeme Tunbridge, Senior Vice President Medical Devices

First Issued: **2019-03-28** Date: **2022-04-22** Expiry Date: **2025-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 708526

Issued To:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Catalogue Number	Device Name	Model, Type	Intended purpose per IFU	Classification
GXHBV-VL-CE-10	Xpert HBV Viral Load	N/A	In vitro nucleic acid amplification test designed for the quantitation of Hepatitis B Virus (HBV) DNA in human serum or plasma (EDTA) from chronically HBV-infected individuals using the automated GeneXpert Systems.	Annex II list A

First Issued: **2019-03-28** Date: **2022-04-22** Expiry Date: **2025-05-26**

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EC Design-Examination Certificate

Supplementary Information to CE 708526

Issued To:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Certificate History

Date	Reference Number	Action
28 March 2019	9738793	First issue. Transfer from another Notified Body.
09 August 2019	3057081	Change: Extension of shelf life to 12 months.
28 August 2020	3277769	Extension to shelf life claim from 12 months to 18 months
14 May 2021	3411740	Amended – PEI batch release wet testing frequency reduced to 1:5 sampling rate per NB-MED/2.5.4/Rec2.
Current	3615745	Renewal.

First Issued: **2019-03-28** Date: **2022-04-22** Expiry Date: **2025-05-26**

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Cepheid
904 Caribbean Drive
Sunnyvale
California
94089
USA

Holds Certificate Number: MD 774674

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

Design, Development, Manufacture and Distribution of Nucleic Acid Test Kits and Reagents used for Monitoring and Patient Management. Design, Development, Manufacture, Service, Installation, Distribution and Refurbishment of Analyzers used for Monitoring and Patient Management.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2022-08-02
Latest Revision Date: 2025-07-10

Effective Date: 2024-12-19
Expiry Date: 2027-12-18

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Certificate No: MD 774674

Location	Registered Activities
Cepheid 904 Caribbean Drive Sunnyvale California 94089 USA	Design and Development, of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management. Manufacture of Components used for Monitoring and Patient Management. Control of Manufacture of Analyzers used for Monitoring and Patient Management.
Cepheid 1339 Moffett Park Drive Sunnyvale California 94089 USA	Design and Development of in-vitro diagnostics and Analyzers used for Monitoring and patient management
Cepheid 1327 Chesapeake Terrace Sunnyvale California 94089 USA	Design and Development of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 1315 Chesapeake Terrace Sunnyvale California 94089 USA	Design and Development of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 918 Caribbean Drive Sunnyvale California 94089 USA	Design and Development of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management. Refurbishment of Analyzers used for Monitoring and Patient Management.
Cepheid 1324 Chesapeake Terrace Sunnyvale California 94089 USA	Design and Development, Purchasing, General Administration of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.

Original Registration Date: 2022-08-02

Effective Date: 2024-12-19

Latest Revision Date: 2025-07-10

Expiry Date: 2027-12-18

Certificate No: MD 774674

Location	Registered Activities
Cepheid 6601 Overlake Pl. Newark California 94560 USA	Design and Development of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 44509 Pacific Commons Blvd. Fremont California 94538 USA	Distribution of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid AB Röntgenvägen 5 SE-171 54 Solna Sweden	Design, Development, Manufacture and Distribution of Nucleic Acid Test Kits and Reagents used for Monitoring and Patient Management. Distribution of Analyzers used for Monitoring and Patient Management
Cepheid AB Mätarvägen 45 196 37 Kungsängen Sweden	Distribution of in-vitro Diagnostics and Analyzers used for Monitoring and Patient Management.
Cepheid 225 North Guild Avenue Lodi California 95240 USA	Manufacture of Plastic Components used for Monitoring and Patient Management
Cepheid 121 N Guild Ave. Lodi California 95240 USA	Manufacture of in-vitro diagnostics used for Monitoring and Patient Management.
Cepheid 850 East Thurman Road Lodi California 95240 USA	Manufacture of Plastic Components used for Monitoring and Patient Management

Original Registration Date: 2022-08-02

Effective Date: 2024-12-19

Latest Revision Date: 2025-07-10

Expiry Date: 2027-12-18

Certificate No: MD 774674

Location	Registered Activities
Cepheid 2550 Great America Way Santa Clara Gateway Santa Clara California 95054 USA	Service, Installation, Support and General Administration of in-vitro diagnostics and Analyzers used for Monitoring and Patient Management.

Original Registration Date: 2022-08-02
Latest Revision Date: 2025-07-10

Effective Date: 2024-12-19
Expiry Date: 2027-12-18

Cepheid®

EC DECLARATION OF CONFORMITY

Manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® HBV Viral Load
Catalogue number(s): GXHBV-VL-CE-10

We, the manufacturer, hereby declare, under our sole responsibility, that the product(s) stated above conforms to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD), (LVFS 2001:7).

Product classification: Annex II, list A
Conformity Assessment route: Annex IV
Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
Notified Body number: 2797
EC Certificate – Full Quality Assurance: CE 708525
EC Design-Examination Certificate: CE 708526

Signed on behalf of Cepheid AB by:

Signature
Lena Kirsel
Senior Manager of Regulatory Affairs

May 23, 2022
Date of Issue

Place of Issue: Solna, Sweden

Cepheid®

EC DECLARATION OF CONFORMITY

Manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden

Product name: Xpert® HCV Viral Load
Catalogue number(s): GXHCV-VL-CE-10

We, the manufacturer, hereby declare, under our sole responsibility, that the product(s) stated above conforms to Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (IVDD), (LVFS 2001:7).

Product classification: Annex II, list A
Conformity Assessment route: Annex IV
Notified Body: BSI Group The Netherlands B.V.
Say Building, John M. Keynesplein 9
1066 EP Amsterdam
The Netherlands
Notified Body number: 2797
EC Certificate – Full Quality Assurance: CE 708525
EC Design-Examination Certificate: CE 708527

Signed on behalf of Cepheid AB by:

Signature
Lena Kirsel
Senior Manager of Regulatory Affairs

May 23, 2022
Date of Issue

Place of Issue: Solna, Sweden

EU DECLARATION OF CONFORMITY

	Cepheid 904 Caribbean Drive Sunnyvale, CA 94089 USA Single Registration Number (SRN): US-MF-000010979
	Cepheid Europe SAS Vira Solelh 81470 Maurens-Scopont France Single Registration Number (SRN): FR-AR-000001368
Device Trade Name	Xpert® Check
Basic UDI-DI	081164701-XPERTCHECK-3B
	XPERTCHECK-CE-5
Device Intended Purpose	**Intended Use:** Xpert Check is part of a check, verification, and hardware test system for GeneXpert modules. Xpert Check is used in GeneXpert Dx, GeneXpert Xpress and Infinity systems, and cannot be used in the GeneXpert Omni system. Xpert Check is used to check the optical system, verify the thermal system and perform a series of system-level tests to ensure full system functionality within Cepheid's instrument servicing specifications. One Xpert Check cartridge is usually used to check a single module in conjunction with the Xpert Check software. In certain cases where a retest is required, multiple cartridges may be necessary to test a module. **Intended User / Environment:** Xpert Check is intended to be performed by trained users where a GeneXpert System is installed.

We, as the manufacturer of the device take sole responsibility for and hereby declare that the above mentioned device meets the provisions of the following Regulation:

Regulation EU 2017/746 on in vitro Diagnostic Medical Devices	
Risk Class	A ☒ B☐ C☐ D☐
Classification Rule	Annex VIII, Rule: Implementing Rule 1.3. Accessory Annex VIII, Rule 5 (b) Accessory to instrument
Conformity Assessment Route	☐ Annex IX(I) Quality Management System ☐ Annex IX(II) Technical Documentation ☐ Annex X Type Examination ☐ Annex XI Production Quality Assurance ☒ Annex II & III (class A only)
Common Specification	Not Applicable
Notified Body	Not Applicable
Notified Body Number	Not Applicable
Certificate(s)	Not Applicable

Signed on behalf of Cepheid by:

Signature

09/06/2024
Date of Issue

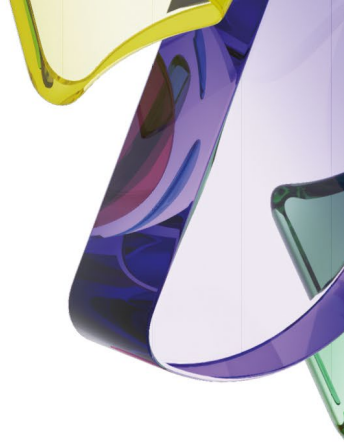
Suzette Chance
Vice President, Regulatory Affairs, NPD

Place of Issue: Sunnyvale, California

Signature: Suzette Chance
Suzette Chance (Sep 8, 2024 06:48 CDT)

Email: Suzette.Chance@cepheid.com

Your partner
in progress



17-FEB-2025

Cepheid AB

Röntgenvägen 5

SE-171 54 Solna

Sweden

Our ref: EU 2024-1860/995792

Notified Body Confirmation Letter

Reference: EU 2024-1860/995792

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, BSI Group The Netherlands B.V., a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) and identified by the number 2797 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the following manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden
SRN Number : SE-MF-000002020

BSI Group The Netherlands B.V.
Say Building John M. Keynesplein 1-27
Amsterdam Bergen 1066 EP
Netherlands
bsigroup.nl

+31 20 346 0780
BSIMedDev.NB2797@bsigroup.com

Validity of this letter may be verified by writing to Certificate.Verification@bsigroup.com

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the Directive 98/79/EC. Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the Directive 98/79/EC.

In the case of devices covered by certificates issued under Directive 98/79/EC (IVD) that expired after 26 May 2022 and before 9th July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54 of IVDR or Article 92 of the IVDR respectively, by the 9th July 2024 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110.3c of IVDR (as amended by (EU) 2024/1860), are shown below:

- 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR
- For devices not requiring the involvement of a notified body under the IVDD, but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:
    - 31 December 2027, for class D devices;
    - 31 December 2028, for class C devices;
    - 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge

Senior Vice President, Medical Devices

BSI Group The Netherlands B.V.
Say Building John M. Keynesplein 1-27
Amsterdam Bergen 1066 EP
Netherlands
bsigroup.nl

+31 20 346 0780
BSIMedDev.NB2797@bsigroup.com

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Xpert HIV-1 Viral Load XC	Class D	N/A	CE 731750, NB 2797 CE 708525, NB 2797
Xpert HIV-1 Qual XC	Class D	N/A	CE 742686, NB 2797 CE 708525, NB 2797
Xpert HCV Viral Load	Class D	N/A	CE 708527, NB 2797 CE 708525, NB 2797
Xpert HCV VL Fingerstick	Class D	N/A	CE 708531, NB 2797 CE 708525, NB 2797
Xpert HBV Viral Load	Class D	N/A	CE 708526, NB 2797 CE 708525, NB 2797
Xpert CT/NG (NPT)	Class C	Xpert CT/NG	CE 708525, NB 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
N/A	N/A	N/A	N/A

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Confirmation Letter Revision History

Date	Action
2024/10/30	Initial issue
2024/10/30	Correction of typo to IVDR Classification in Table 1. Add IVDR device substitution names in Table 1 and 2.
2025/02/17	Add IVDD FQA certificate reference to Class D devices in Table 1. Removal of Xpert Xpress CoV-2 plus and Xpert Xpress CoV-2/Flu/RSV plus.

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Validity of this letter may be verified by writing to Certificate.Verification@bsigroup.com

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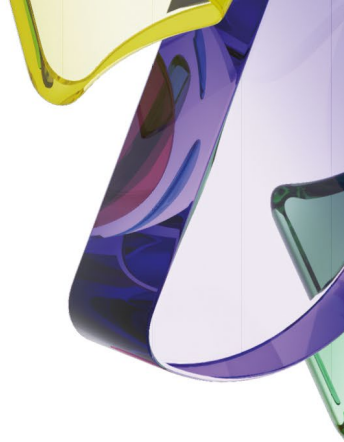

02-JUL-2025

Cepheid AB

Röntgenvägen 5

SE-171 54 Solna

Sweden

Our ref: EU 2024-1860/995792

Notified Body Confirmation Letter

Reference: EU 2024-1860/995792

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2024/1860 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, BSI Group The Netherlands B.V., a Notified Body (NB) designated against Regulation (EU) 2017/746 (IVDR) and identified by the number 2797 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of IVDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of IVDR with the following manufacturer:

Cepheid AB
Röntgenvägen 5
SE-171 54 Solna
Sweden
SRN Number : SE-MF-000002020

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The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an IVDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the Directive 98/79/EC. Table 2 identifies the devices for which an IVDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the Directive 98/79/EC.

In the case of devices covered by certificates issued under Directive 98/79/EC (IVD) that expired after 26 May 2022 and before 9th July 2024, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under IVDR by the date of IVDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 54 of IVDR or Article 92 of the IVDR respectively, by the 9th July 2024 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 110.3c of IVDR (as amended by (EU) 2024/1860), are shown below:

- 31 December 2027 for devices covered by an IVDD certificate regardless of their risk class under the IVDR
- For devices not requiring the involvement of a notified body under the IVDD, but requiring it under the IVDR and for which a declaration of conformity was drawn up prior to 26 May 2022 in accordance with Directive 98/79/EC, the following dates apply:
    - 31 December 2027, for class D devices;
    - 31 December 2028, for class C devices;
    - 31 December 2029, for class B devices and for class A devices placed on the market in sterile condition

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge

Senior Vice President, Medical Devices

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Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under Directive 98/79/EC:

Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Xpert HIV-1 Viral Load XC	Class D	N/A	CE 731750, NB 2797 CE 708525, NB 2797
Xpert HIV-1 Qual XC	Class D	N/A	CE 742686, NB 2797 CE 708525, NB 2797
Xpert HCV Viral Load	Class D	N/A	CE 708527, NB 2797 CE 708525, NB 2797
Xpert HCV VL Fingerstick	Class D	N/A	CE 708531, NB 2797 CE 708525, NB 2797
Xpert HBV Viral Load	Class D	N/A	CE 708526, NB 2797 CE 708525, NB 2797
Xpert CT/NG (NPT)	Class C	Xpert CT/NG	CE 708525, NB 2797

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

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Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
Xpert® HPV v2 **(GXHPV2-CE-10)**	Class C	Xpert® HPV GXHPV-CE-10	N/A - Device did not require a Notified Body certificate under Directives
Xpert® Xpress GBS **(XPRSGBS-CE-10)**	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directives
Xpert® MRSA/SA Blood Culture **(GXMRSA/SABC-CE-10)**	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directives
Xpert® MRSA/SA SSTI **(GXMRSA/SA-SSTI-CE)**	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directives
Xpert® MRSA NxG **(GXMRSA-NXG-CE-10)**	Class C	Xpert® MRSA NxG GXMRSA-NXG-CE-10, -120)	N/A - Device did not require a Notified Body certificate under Directives
Xpert® MTB/RIF Ultra **(GXMTB/RIF-ULTRA-10, GXMTB/RIF-ULTRA-50)**	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directives
Xpert® MTB XDR **(GXMTB/XDR-10)**	Class C	N/A	N/A - Device did not require a Notified

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Device name or Basic UDI-DI (under IVDR application)	IVDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the IVDR device is a substitute device, identification of the corresponding IVDD device	IVDD Certificate Reference(s) of the devices under IVDR application, and the NB Identification
			Body certificate under Directives
Xpert® SA Nasal Complete (GXSACOMP-CE-10)	Class C	N/A	N/A - Device did not require a Notified Body certificate under Directives
Xpert® C. Difficile BT (GXCDIFFBT-CE-10)	Class B	N/A	N/A - Device did not require a Notified Body certificate under Directives
Xpert® vanA/vanB (GXVANA/B-CE-10)	Class B	N/A	N/A - Device did not require a Notified Body certificate under Directives
Xpert® Norovirus (GXNOV-CE-10)	Class B	N/A	N/A - Device did not require a Notified Body certificate under Directives

Confirmation Letter Revision History

Date	Action
2024/10/30	Initial issue
2024/10/30	Correction of typo to IVDR Classification in Table 1. Add IVDR device substitution names in Table 1 and 2.

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Date	Action
2025/02/17	Add IVDD FQA certificate reference to Class D devices in Table 1. Removal of Xpert Xpress CoV-2 plus and Xpert Xpress CoV-2/Flu/RSV plus.
2025/07/02	Addition of devices in Table 2.

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