Anexa nr. 7
la Documentaţia standard nr.____
din "___" _____ 20__

CERERE DE PARTICIPARE

Către: **IMSP Spitalul Clinic Republican „Timofei Moşneaga",**
(mun.Chişinău, str.N.Testemiţanu 29)

Stimaţi domni,

Ca urmare a anunţuluii de participare apărut în Buletinul achiziţiilor publice nr. 89 din 10.11.2023 şi Jurnalul Oficial al Uniunii Europene, nr. 2023/S 217-681338 din 06.11.2023, privind aplicarea procedurii pentru atribuirea contractului de **achiziţionare a Reagenţilor şi consumabilelor – sistem închis pentru anul 2024**, noi **Medist Grup SRL** (denumirea/numele ofertantului/candidatului), am luat cunoştinţă de condiţiile şi de cerinţele expuse în documentaţia de atribuire şi exprimăm prin prezenta interesul de a participa, în calitate de ofertant/candidat, neavînd obiecţii la documentaţia de atribuire.

Data completării 27.11.2023

Digitally signed by Anghel Gabriela-Cristina
Date: 2023.11.27 17:41:52 EET
Reason: MoldSign Signature
Location: Moldova

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 Chişinău, 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 Chişinău
IBAN (MDL):MD57VI022242600000269MDL
SWIFT: VICBMD2X469

ORDIN DE PLATA NR.477 Tip.doc. 1

DATA EMITERII: 27 noiembrie 2023

PLATITI:5966-00 LEI: Cinci Mii Noua Sute Sasezeci si Sase, 00

PLATITOR: (R)MEDIST GRUP SRL CODUL IBAN:MD57VI022242600000269MDL
CODUL FISCAL:1018600004516

PRESTATORUL PLATITOR
B.C VictoriaBank S.A. s.26 Chisinau

BENEFICIAR:(R) IMSP Spitalul Clinic Republican Timofei Mosneaga CODUL IBAN:MD57MO2251ASV96476607100
CODUL FISCAL:1003600150783

PRESTATORUL BENEFICIAR
OTP Bank

DESTINATIA PLATII: Garantia pentru oferta la LP nr . 21117595 din 14.11.2023.

NORMAL/URGENT:NO

L.S.

CODUL TRANZACTIEI:001

DATA PRIMIRII: _____

DATA EXECUTARII: _____

SEMNATURILE EMITENTULUI

_____
SEMNATURA PRESTATORULUI

MOTIVUL REFUZULUI

L.S.

«VICTORIABANK»
DIRECȚIA OPERAȚIUNI
27. NOI. 2023
Cod fiscal 1002600001338 SWIFT VICBMD2X
Cod IBAN MD81VI0000000000235216701

15:45:18 27 NOV 2023
Semnatura electronica:
WMaL/IyIUkfHXe3zoyfrxck6fimyg9SguLy1XEEDRyFnguFkElRt4nu1Q2ZTi4jTmYUMjRjeAAzL
7potwXVvnfR1Ntn1YoCK35oG56KcGpy/qxMK4CImGGtCRTdnq+5BoBs5q0F7/wVtYvAceiVtHR0b
dlL8znCRzjjX2+tfufcLyaTQ/6c26kYwdy/y+pCbjdub7MUF31yAuj1somgO7B3dUMlScHY9x/Sd
B0nf9hd6ib4N29Qjo2cRj/wz1KpKWdNvkEbTK2S85cnauxHgTurQ6DFbJLkJLddySVu31nGJ1eK4
UOTaVSql52mSEiRULahv94o2MWRbhc3bJVPdHA==

I.P. "AGENȚIA SERVICII PUBLICE"
Departamentul înregistrare și licențiere a unităților de drept

Extras
din Registrul de stat al persoanelor juridice
nr. **117493** din **15.09.2023**

Denumirea completă: **Societatea cu Răspundere Limitată "MEDIST GRUP"**
Denumirea prescurtată: **"MEDIST GRUP" S.R.L.**
Forma juridică de organizare: **Societate cu răspundere limitată**
Numărul de identificare de stat și codul fiscal: **1018600004516**
Data înregistrării de stat: **02.02.2018**
Sediu: **MD-2012, strada Mitropolit Gavriil Bănulescu-Bodoni 25, ap. 33, mun. Chişinău, Republica Moldova**
Genurile de activitate:

1. **Comerţ cu ridicata al produselor farmaceutice;**
2. **Comerţ cu ridicata nespecializat;**
3. **Repararea echipamentelor electronice şi optice;**
4. **Activităţi de testare şi analize tehnice;**
5. **Comerţ cu amănuntul al articolelor medicale şi ortopedice, în magazine specializate;**

Capitalul social: **373026 Lei**
Administrator: **ANGHEL GABRIELA-CRISTINA IDNP 2017803985939**
Asociați:

1. **MEDIST IMAGING & P.O.C. S.R.L., partea socială 6244 Euro, ce constituie 33.00%**
2. **MEDIST LIFE SCIENCE S.R.L., partea socială 6244 Euro, ce constituie 33.00%**
3. **MEDIST S.R.L., partea socială 6433 Euro, ce constituie 34.00%**

Beneficiari efectivi: **MANOLE IONEL, KLUMPNER CATALINA ANA, VLĂDESCU CARMEN, VLĂDESCU SEBASTIAN-ALEXANDRU**

Prezentul extras este eliberat în temeiul art. 34 al Legii nr.220/2007 privind înregistrarea de stat a persoanelor juridice şi a întreprinzătorilor individuali şi confirmă datele din Registrul de stat la data de 15.09.2023

Specialist coordonator
Marina Franţuz
tel. 022-207837

DECLARAŢIE
privind valabilitatea ofertei

Către: **IMSP Spitalul Clinic Republican „Timofei Moșneaga”**

Stimaţi domni,

Ne angajăm să menţinem oferta valabilă, **privind achiziţionarea Reagenţilor şi consumabilelor – sistem închis pentru anul 2024 prin procedura de achiziţie licitaţie deschisă,** pentru o durată de 90 zile, (noua zeci), respectiv până la data de 30/03/2024 (ziua/luna/anul), şi ea va rămâne obligatorie pentru noi şi poate fi acceptată oricând înainte de expirarea perioadei de valabilitate.

Data completării 27.11.2023

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

MEDIST Grup

Soluții pentru sănătate

DECLARAȚIE

Subsemnata Gabriela Anghel, reprezentant împuternicit al MEDIST GRUP S.R.L, cu sediul în mun. Chișinău, str. M.G. Bănulescu-Bodoni 25, Oficiul 33, declar pe propria răspundere că:

- Livrarea produselor va avea loc cu respectarea condițiilor de păstrare și transportare;
- Seturile vor fi livrate în ambalaj original, securizat, marcat şi etichetat de producător, fără preambalare;
- Date de identitate (denumirea, numărul lotului, seria, termenii de valabilitate, condiţiile de păstrare) ale produsului indicate pe ambalaj coincid în mod obligatoriu cu cele de pe etichetele componentelor incluse în set.
- Instrucţiunile de utilizare a truselor vor conţine caracteristicile de performanţă şi calitate: sensibilitatea, liniaritatea, specificitatea, reproductibilitatea şi interferenţa.
- Instrucţiunile privind modul de utilizare vor fi prezentate în limba de stat sau limba rusă.
- Reagenţii, soluţiile din set vor fi in stare lichidă şi gata de lucru, în cazul cînd nu sînt liofilizaţi. Soluţiile de lucru vor fi stabile conform instrucţiunilor indicate de producător.
- In instrucţiunea de folosire vor fi indicate specificitatea şi sensibilitatea testelor. Cerințe conform ordinului MS nr.701 din 18.10.2010.
- Termenul de valabilitate restant (la momentul livrării va constitui cel puțin 80% din termenul total al produsului), mai puțin pentru produsele confirmate de producător cu o valabilitate scurtă de viață si perioada de transportare mare de la SUA până la Repubica Moldova (confirmarea se atașează):
- 800-3104 IQ Control/Focus Set
- 800-3103 IQ Calibrator Pack
- 800-7702 Irispec CA/CB/CC
- Ne asumăm să prezentăm mostrele în decurs de 5 zile calendaristice de la solicitare;
- Bunurile ce urmează a fi achiziționate sunt înregistrate în Registrul de Stat al Dispozitivelor Medicale, mai jos dovada:

REGISTRUL DE STAT AL DISPOZITIVELOR MEDICALE

Введите текст для поиска...

Nr	Denumire	Den.comerc.	Model	Nr. catalog	Tara	Producatorul	Reprezentant	Ordin	Data	Cod vamal
				800-7217						
DM000358849	SET DE REACTIVI PENTRU ANALIZE		ICHEM VELOCITY WASH SOLUTION	800-7217	Irlanda	BECKMAN COULTER IRELAND INC.,	MEDIST GRUP S.R.L.	Rg04-000155	30-06-2022	
DM000358847	SET DE REACTIVI PENTRU ANALIZE		IQ LAMINA	800-3236	Irlanda	BECKMAN COULTER IRELAND INC.,	MEDIST GRUP S.R.L.	Rg04-000155	30-06-2022	
DM000358848	SET DE REACTIVI PENTRU ANALIZE		ICHEM VELOCITY URINE CHEMISTRY STRIPS	800-7204	Irlanda	BECKMAN COULTER IRELAND INC.,	MEDIST GRUP S.R.L.	Rg04-000155	30-06-2022	
DM000358844	SET DE REACTIVI PENTRU ANALIZE		IQ CONTROL LFOCUS SET	800-3104	Irlanda	BECKMAN COULTER IRELAND INC.,	MEDIST GRUP S.R.L.	Rg04-000155	30-06-2022	
DM000358843	SET DE REACTIVI PENTRU ANALIZE		IQ CALIBRATOR PACK	800-3103	Irlanda	BECKMAN COULTER IRELAND INC.,	MEDIST GRUP S.R.L.	Rg04-000155	30-06-2022	
DM000358851	SET DE REACTIVI PENTRU ANALIZE		ICHEM VELOCITY CALCHEK KIT	800-7703	Irlanda	BECKMAN COULTER IRELAND INC.,	MEDIST GRUP S.R.L.	Rg04-000155	30-06-2022	
DM000358846	SET DE REACTIVI PENTRU ANALIZE		IRIS SYSTEM CLEANSER PACK	800-3203	Irlanda	BECKMAN COULTER IRELAND INC.,	MEDIST GRUP S.R.L.	Rg04-000155	30-06-2022	
DM000358845	SET DE REACTIVI PENTRU ANALIZE		IRIS DILUENT	800-3202	Irlanda	BECKMAN COULTER IRELAND INC.,	MEDIST GRUP S.R.L.	Rg04-000155	30-06-2022	

Pentru bunurile care nu sunt deja înregistrare, atașăm documentația necesară înregistrării. **Data completării 27.11.2023**

Cu stimă,

Ofertant/candidat

Gabriela-Cristina Anghel

Nyon, September 8th, 2022

REF: MEDIST SRL
STR ION URDAREANU 34
SECTOR 5
050688 BUCHAREST
Romania

To whom it may concern,

Beckman Coulter International SA, hereby, notifies that due to transportation lead time from and to our warehouses as well as unforeseeable events beyond our control, the below listed items may be delivered with shorter expiry date than the guaranteed dating. Nevertheless, the approximate expiry date remains around 4 months.

Item	Item description	Guaranteed dating
800-3104	IQ Control/Focus Set	**180 days**
800-3103	IQ Calibrator Pack	**180 days**
800-7702	Irispec CA/CB/CC Package	**142 days**

Thank you very much for your understanding.

Yours truly,

DocuSigned by:
Alistair Jones
738375E0F6A94AB...

BECKMAN COULTER INTERNATIONAL S.A.
22, rue Juste-Olivier
Case Postale 1059
1260 Nyon - Switzerland

Beckman Coulter International SA
Alistair Jones

MEDIST Grup

Soluții pentru sănătate

Către: Agenţia Medicamentului şi Dispozitivelor Medicale

NOTIFICARE

pentru reînregistrarea dispozitivelor medicale în Registrul de stat al dispozitivelor medicale

nr. 13 din 27.11.2023

Solicitantul MEDIST Grup S.R.L., cu sediul în Republica Moldova, Chişinău. Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25, oficiul 33, tel./fax: +373 022 84 94 95, solicit reînregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru reintroducerea şi punerea la dispoziţie pe piaţă a:

- reactivi pentru analiza urinei produsă în Irlanda: IVD general - Anexa VIII;

Se anexează următoarele acte:
- Reactivi pentru analiza urinei produsă în Irlanda;
- Declaraţie de conformitate CE;
- Împuternicire producător – Beckman Coulter Ireland-Beckman Coulter S.A;
- Împuternicire producător Beckman Coulter S.A – Medist Grup SRL
- Declaraţie pe proprie răspundere – MEDIST Grup S.R.L.

Data: 27.11.2023 Semnătura

Tabelul de recepţionare a notificării
(se completează de către Agenţie în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepţionării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenţie (în cazul acceptării recepţionării)	
Numele, prenumele, funcţia persoanei responsabile de recepţionarea dosarului	
Semnătura persoanei responsabile	

MEDIST Grup S.R.L.
Str. Mitropolit Gavriil Bănulescu-Bodoni nr. 25
Oficiul 33, MD-2012 Chişinău, Rep. Moldova
Tel./Fax: +373 022 84 94 95
E-mail: office@medist.md
Web: www.medist.md

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

DECLARATION OF CONFORMITY

Not classified as hazardous

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

Beckman Coulter Ireland Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the *In-Vitro* Diagnostic Medical Devices Regulation 2017/746.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Product(s):
Iris Diluent - PN 800-3202

Device Group:
W02039085

BUDI-DI:
150995902UADILUENTMY

Risk Class:
Class A, Rule 5 (Article 47 in accordance with Annex VIII)

Intended Purpose:
Iris Diluent is intended for in vitro diagnostic use with iQ200 or DxU 840/850m Series of Automated Urine Microscopy Analyzers. It is a particle free aqueous salt solution which is used for diluting urine and body fluid samples. It is also used to rinse the system to prevent carryover of system cleaner and samples. The device is intended to be used by a laboratory professional.

Common Specification(s):
None

Authorized Representative (AR)
N/A

AR SRN: N/A

Conformity Assessment Procedure:
Conformity Assessment based on a Quality Management System and on Technical Documentation in accordance with Annex II and III, and declaration of conformity in accordance with Article 17 and Annex IV.

Signed for and on behalf of Beckman Coulter Ireland, Inc. the Legal Manufacturer.

Name: Nery Ortiz 2022-07-06
Title: Sr. Manager Regulatory Affairs, PRRC
Place of Issue: Beckman Coulter, Inc., Miami, FL USA

Notified Body

N/A - Self Declared

Product Certificate Number: N/A

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. MEDIST GRUP IDNO 1018600004516 REPUBLICA MOLDOVA, mun.CHIȘINĂU

COPIA CORESPUNDE ORIGINALULUI

	Beckman Coulter Ireland, Inc. Lismeehan, O'Callaghan's Mills Co. Clare Ireland +(353) (0) 65 683 1100 **Manufacturer SRN:** IE-MF-000000887	**Document Control**	
		Issue Date: **Revision Level:** **Starting :** **DoC Filename:**	2022-05-03 1.3 April 28th, 2022 IRL-0097 DOC

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. MEDIST GRUP IDNO 1018600004516 REPUBLICA MOLDOVA, mun. CHIȘINĂU

COPIA CORESPUNDE ORIGINALULUI

English

DECLARATION OF CONFORMITY

Iris System Cleanser

DANGER

H314	Causes severe skin burns and eye damage.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Rinse skin with water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/physician.
	Sodium Hydroxide 0.1 - 1%
	Sodium Hypochlorite 1 - 5%

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

Beckman Coulter Ireland Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the *In-Vitro* Diagnostic Medical Devices Regulation 2017/746.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Product(s):
Iris System Cleanser – 800-3203

Device Group:
W02039085

BUDI-DI:
150995902UACLEANSER88

Risk Class:
Class A, Rule 5 (Article 47 in accordance with Annex VIII)

Intended Purpose:
Iris System Cleanser is intended for in vitro diagnostic use with iQ200 or DxU 840/850m Series of Automated Urine Microscopy Analyzers and iChemVELOCITY or DxU 810c Automated Urine Chemistry Analyzer. Iris System Cleanser is a ready-for-use solution specifically developed as a wash solution for the iQ200 or DxU 840/850m Series of Automated Urine Microscopy Analyzers. For the iChemVELOCITY and DxU 810c Automated Urine Chemistry Analyzers, the Iris System Cleanser is used as a cleaning solution. A wash cycle must be performed at the beginning of each work day to prevent accumulation of residue in the fluidic system, sample lines and flow cell. The device is intended to be used by a laboratory professional.

Common Specification(s):
None

Authorized Representative (AR)
N/A

AR SRN: N/A

Conformity Assessment Procedure:
Conformity Assessment based on a Quality Management System and on Technical Documentation in accordance with Annex II and III, and declaration of conformity in accordance with Article 17 and Annex IV

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. MEDIST GRUP IDNO 1018600004516 REPUBLICA MOLDOVA, mun.CHISINAU

COPIA CORESPUNDE ORIGINALULUI

Signed for and on behalf of Beckman Coulter Ireland, Inc. the Legal Manufacturer. Nery Ortiz **Name:** Nery Ortiz 2022-07-06 **Title:** Sr. Manager Regulatory Affairs, PRRC **Place of Issue:** Beckman Coulter, Inc., Miami, FL USA		**Notified Body** N/A - Self Declared **Product Certificate Number:** N/A
	Beckman Coulter Ireland, Inc. Lismeehan, O'Callaghan's Mills Co. Clare Ireland +(353) (0) 65 683 1100 **Manufacturer SRN:** IE-MF-000000887	**Document Control** **Issue Date:** 2022-04-26 **Revision Level:** 1.2 **Starting :** April 28th, 2022 **DoC Filename:** IRL-0096 DOC

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. MEDIST GRUP IDNO 1018600004516 REPUBLICA MOLDOVA, mun.CHIȘINĂU

COPIA CORESPUNDE ORIGINALULUI

DECLARATION OF CONFORMITY

iQ Lamina (Part A)	EUH208	May produce an allergic reaction. N-(3-Chloroallyl)hexaminium Chloride < 0.1%

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

Beckman Coulter Ireland Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the *In-Vitro* Diagnostic Medical Devices Regulation 2017/746.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Product(s):
iQ Lamina - PN 800-3236

Device Group:
W02039085

BUDI-DI:
150995902UALAMINA39

Risk Class:
Class A, Rule 5 (Article 47 in accordance with Annex VIII)

Intended Purpose:
iQ Lamina is intended for in vitro diagnostic use with the iQ200 or DxU 840/850m Series of Automated Urine Microscopy Analyzers. It is used to hydrodynamically position the flow of specimen within the focal depth of the lens of the microscope and to ensure streamlined flow by rinsing and wetting all fluidic components. The device is intended to be used by a laboratory professional.

Common Specification(s):
None

Authorized Representative (AR)
N/A

AR SRN: N/A

Conformity Assessment Procedure:
Conformity Assessment based on a Quality Management System and on Technical Documentation in accordance with Annex II and III, and declaration of conformity in accordance with Article 17 and Annex IV.

Signed for and on behalf of Beckman Coulter Ireland, Inc. the Legal Manufacturer.

Notified Body

N/A - Self Declared

Name: Nery Ortiz 2022-07-06
Title: Sr. Manager Regulatory Affairs, PRRC
Place of Issue: Beckman Coulter, Inc., Miami, FL USA

Product Certificate Number: N/A

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. MEDIST GRUP IDNO 1018600004516 REPUBLICA MOLDOVA, mun.CHIȘINĂU

COPIA CORESPUNDE ORIGINALULUI

	Beckman Coulter Ireland, Inc. Lismeehan, O'Callaghan's Mills Co. Clare Ireland +(353) (0) 65 683 1100 **Manufacturer SRN:** IE-MF-000000887	**Document Control**	
		Issue Date: **Revision Level:** **Starting Lot:** **DoC Filename:**	2022-04-20 1.2 151-22M IRL-0095 DOC

DECLARATION OF CONFORMITY

Not classified as hazardous

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

Beckman Coulter Ireland Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the *In-Vitro* Diagnostic Medical Devices Regulation 2017/746.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Product(s):
iChemVELOCITY Wash Solution - PN 800-7217

Device Group:
W02039085

BUDI-DI:
150995902UAWASHSOLW6

Risk Class:
Class A, Rule 5 (Article 47 in accordance with Annex VIII)

Intended Purpose:
The iChemVELOCITY Wash Solution is a buffer solution for routine rinse of the iChemVELOCITY or DxU 810c Series of Automated Urine Chemistry Analyzers. This reagent is intended for in vitro diagnostic use with the iChemVELOCITY or DxU 810c Series of Automated Urine Chemistry Analyzers. It is a ready-for-use solution specifically developed for the application in the iChemVELOCITY or DxU 810c Series of Automated Urine Chemistry Analyzers. Use of this Wash Solution properly provides the optimal operating condition for the System. The device is intended to be used by a laboratory professional.

Common Specification(s):
None

Authorized Representative (AR)
N/A

AR SRN: N/A

Conformity Assessment Procedure:
Conformity Assessment based on a Quality Management System and on Technical Documentation in accordance with Annex II and III, and declaration of conformity in accordance with Article 17 and Annex IV.

Signed for and on behalf of Beckman Coulter Ireland, Inc. the Legal Manufacturer.

Notified Body

N/A - Self Declared

Name: Nery Ortiz 2022-07-06
Title: Sr. Manager Regulatory Affairs, PRRC
Place of Issue: Beckman Coulter, Inc., Miami, FL USA

Product Certificate Number: N/A

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. MEDIST GRUP IDNO 1018600004516 REPUBLICA MOLDOVA, mun. CHIȘINĂU

COPIA CORESPUNDE ORIGINALULUI

	Beckman Coulter Ireland, Inc. Lismeehan, O'Callaghan's Mills Co. Clare Ireland +(353) (0) 65 683 1100 **Manufacturer SRN:** IE-MF-000000887	**Document Control**	
		Issue Date: **Revision Level:** **Starting :** **DoC Filename:**	2022-04-26 1.2 April 27th, 2022 IRL-0099 DOC

BECKMAN COULTER

To whom it may concern

February 5, 2018

Re: Appointment of MEDIST GRUP S.R.L.

Dear Sir/Madam:

We, Beckman Coulter International S.A., a subsidiary of Beckman Coulter Inc., a manufacturer of medical equipment and reagents, having our headquarters at 22 Rue Juste-Olivier, 1260 Nyon, Switzerland, appoint MEDIST GRUP S.R.L., located in 25 Mitropolit Gavriil Banulescu-Bodoni Street, office no. 33, Chisinau, Republic of Moldova, to represent us in front of the local authorities of Republic of Moldova in what concerns the registration/notification of medical devices with the Agency of Medicine and Medical Devices according to law no. 102/2017.

Sincerely,

Arno Schoenberger

Director Marketing, Selling & Marketing

BECKMAN COULTER INTERNATIONAL S.A.
22, RUE JUSTE-OLIVIER
CASE POSTALE 1059
1260 NYON-1 - SWITZERLAND

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
MEDIST GRUP
IDNO 1018600004516
REPUBLICA MOLDOVA, mun.CHIȘINĂU

COPIA CORESPUNDE ORIGINALULUI

BECKMAN COULTER

May 5, 2022

TO WHOM IT MAY CONCERN

We, Beckman Coulter, Inc. and Beckman Coulter Ireland Inc., having our headquarters respectively at 250 S. Kraemer Boulevard, Brea, California 92821 USA and at Lismeehan, O'Callaghan's Mills, Co. Clare, Ireland,

HEREBY DECLARE

that we are the manufacturers of medical equipment and reagents for the Chemistry product line and empower Beckman Coulter International S.A. located at 22, rue Juste-Olivier, 1260 Nyon – Switzerland to represent us in front of the local authorities of the Republic of Moldova by the medium of MEDIST Group S.R.L. during the registration/notification process of medical devices with the Agency of Medicine and Medical Devices (according to law no. 102/2017).

In witness whereof,

Sincerely,

Jason Elfenbein
Assistant Secretary
Beckman Coulter, Inc.

Paul Henry

Paul Henry
Director
Beckman Coulter Ireland Inc.

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. MEDIST GRUP IDNO 1018600004516 REPUBLICA MOLDOVA, mun. CHIȘINĂU

COPIA CORESPUNDE ORIGINALULUI

MEDIST Grup

Soluții pentru sănătate

Către: **Agenţia Medicamentului şi Dispozitivelor Medicale**

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitantul MEDIST Grup S.R.L., înregistrat la Camera de Înregistrare de Stat cu seria 10186000004516 / 02.02.2018, cu sediul în Str. Bănulescu Bodoni 25, of. 33, Chișinău, MD-2012, declar pe proprie răspundere, cunoscând prevederile art. 352[1] din Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele şi datele furnizate pentru notificarea dispozitivului medical:

- *reactivi pentru analiza urinei produsă în Irlanda: IVD general Class A - Anexa VIII*

sunt autentice şi corespund realităţii.

Gabriela Anghel,

Directoare administrativă

Semnătura _____

Data 27.01.2023

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):MD57VI0222426000000269MDL
SWIFT: VICBMD2X469

Lista dispozitivelor medicale solicitate spre notificare - reactivi analiză urini marca Beckman Coulter - Produs Irlanda

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod EMDN*
1	800-3202	Iris Diluent	Beckman Coulter Ireland, Inc.	Iris Diluent	W02039085
2	800-3203	Iris System Cleanser Pack	Beckman Coulter Ireland, Inc.	Iris System Cleanser Pack	W02039085
3	800-3236	iQ Lamina	Beckman Coulter Ireland, Inc.	iQ Lamina	W02039085
4	800-7217	iChem VELOCITY Wash Solution	Beckman Coulter Ireland, Inc.	iChem VELOCITY Wash Solution	W02039085

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare
Ireland

Holds Certificate Number: **MD 670660**

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

The design and development, manufacture, distribution, installation, service and customer support of clinical chemistry, haematology, heterogenous immunoassay and flow cytometry in vitro diagnostic devices. Manufacture and distribution of infectious disease immunoassays.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Medical Devices

Original Registration Date: 2017-04-12
Effective Date: 2021-11-21
Latest Revision Date: 2022-04-06
Expiry Date: 2024-11-20

...making excellence a habit.™

Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produckte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listadoes a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name	Part Number (PN)
iQ Calibrator (Pack)	800-3103

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General IVD (non Annex II, non self test)

GMDN Code(s):
42064

Nery Ortiz
Sr. Manager Regulatory Affairs

07 Feb 2019
Date

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level:1.0
Revision Date:12/14/2018
Starting Lot #: N/A
Filename: 8003103DEC

Section 1 – Product Identification

Product Name	Part Number (PN)
iQ Calibrator (Pack)	800-3103

Section 2 – CE Status

☒ First Issue ☐ Revision /Revision No.1.0

Reason for Revision (if applicable):
N/A-Initial Issue

Section 3 – Standards Applied to Demonstrate Compliance with Directives Below:

EN ISO 13485:2016
EN ISO 14971:2012
EN ISO 18113-1:2011
EN ISO 18113-2:2011
EN ISO 15223-1:2016

Section 4 – Compliance with Essential Requirements

The product identified in this Technical File Information Sheet has been evaluated in accordance with the Directives and Harmonized Standards identified on the corresponding Declaration of Conformity as attested to below:

				Responsible Individual		
Directive	**Standards Applied in Full**	**Compliant**	**Project Number**	**Name**	**Date**	**Signature**
98/79/EC in vitro Diagnostic Medical Devices	Yes	Yes	9088	Nery Ortiz	07 Feb 2019	Nery Ortiz

Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produckte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listadoes a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name	Part Number (PN)
iQ Control/Focus Set	800-3104

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General IVD (non Annex II, non self test)

GMDN Code(s):
42064

Nery Ortiz
Sr. Manager Regulatory Affairs

07 Feb 2019
Date

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level:1.0
Revision Date:12/14/2018
Starting Lot #: N/A
Filename: 8003104DEC

DECLARATION OF CONFORMITY

Not classified as hazardous

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

Beckman Coulter Ireland Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the *In-Vitro* Diagnostic Medical Devices Regulation 2017/746.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Product(s):
Iris Diluent - PN 800-3202

Device Group:
W02039085

BUDI-DI:
150995902UADILUENTMY

Risk Class:
Class A, Rule 5 (Article 47 in accordance with Annex VIII)

Intended Purpose:
Iris Diluent is intended for in vitro diagnostic use with iQ200 or DxU 840/850m Series of Automated Urine Microscopy Analyzers. It is a particle free aqueous salt solution which is used for diluting urine and body fluid samples. It is also used to rinse the system to prevent carryover of system cleaner and samples. The device is intended to be used by a laboratory professional.

Common Specification(s):
None

Authorized Representative (AR)
N/A

AR SRN: N/A

Conformity Assessment Procedure:
Conformity Assessment based on a Quality Management System and on Technical Documentation in accordance with Annex II and III, and declaration of conformity in accordance with Article 17 and Annex IV.

Signed for and on behalf of Beckman Coulter Ireland, Inc. the Legal Manufacturer.

Name: Nery Ortiz 2022-07-06
Title: Sr. Manager Regulatory Affairs, PRRC
Place of Issue: Beckman Coulter, Inc., Miami, FL USA

Notified Body

N/A - Self Declared

Product Certificate Number: N/A

	Beckman Coulter Ireland, Inc. Lismeehan, O'Callaghan's Mills Co. Clare Ireland +(353) (0) 65 683 1100 **Manufacturer SRN:** IE-MF-000000887	**Document Control**	
		Issue Date: **Revision Level:** **Starting :** **DoC Filename:**	2022-05-03 1.3 April 28th, 2022 IRL-0097 DOC

DECLARATION OF CONFORMITY

Iris System Cleanser

DANGER

H314	Causes severe skin burns and eye damage.
H400	Very toxic to aquatic life.
H411	Toxic to aquatic life with long lasting effects.
P273	Avoid release to the environment.
P280	Wear protective gloves, protective clothing and eye/face protection.
P301+P330+P331	IF SWALLOWED: rinse mouth. Do NOT induce vomiting.
P303+P361+P353	IF ON SKIN (or hair): Rinse skin with water.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER or doctor/physician.
	Sodium Hydroxide 0.1 - 1%
	Sodium Hypochlorite 1 - 5%

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

Beckman Coulter Ireland Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the *In-Vitro* Diagnostic Medical Devices Regulation 2017/746.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Product(s):
Iris System Cleanser – 800-3203

Device Group:
W02039085

BUDI-DI:
150995902UACLEANSER88

Risk Class:
Class A, Rule 5 (Article 47 in accordance with Annex VIII)

Intended Purpose:
Iris System Cleanser is intended for in vitro diagnostic use with iQ200 or DxU 840/850m Series of Automated Urine Microscopy Analyzers and iChemVELOCITY or DxU 810c Automated Urine Chemistry Analyzer. Iris System Cleanser is a ready-for-use solution specifically developed as a wash solution for the iQ200 or DxU 840/850m Series of Automated Urine Microscopy Analyzers. For the iChemVELOCITY and DxU 810c Automated Urine Chemistry Analyzers, the Iris System Cleanser is used as a cleaning solution. A wash cycle must be performed at the beginning of each work day to prevent accumulation of residue in the fluidic system, sample lines and flow cell. The device is intended to be used by a laboratory professional.

Common Specification(s):
None

Authorized Representative (AR)
N/A

AR SRN: N/A

Conformity Assessment Procedure:
Conformity Assessment based on a Quality Management System and on Technical Documentation in accordance with Annex II and III, and declaration of conformity in accordance with Article 17 and Annex IV.

Signed for and on behalf of Beckman Coulter Ireland, Inc. the Legal Manufacturer.  **Name:** Nery Ortiz 2022-07-06 **Title:** Sr. Manager Regulatory Affairs, PRRC **Place of Issue:** Beckman Coulter, Inc., Miami, FL USA		**Notified Body** N/A - Self Declared **Product Certificate Number:** N/A
	Beckman Coulter Ireland, Inc. Lismeehan, O'Callaghan's Mills Co. Clare Ireland +(353) (0) 65 683 1100 **Manufacturer SRN:** IE-MF-000000887	**Document Control** **Issue Date:** 2022-04-26 **Revision Level:** 1.2 **Starting :** April 28th, 2022 **DoC Filename:** IRL-0096 DOC

DECLARATION OF CONFORMITY

iQ Lamina (Part A)	EUH208	May produce an allergic reaction. N-(3-Chloroallyl)hexaminium Chloride < 0.1%

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

Beckman Coulter Ireland Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the *In-Vitro* Diagnostic Medical Devices Regulation 2017/746.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Product(s):
iQ Lamina - PN 800-3236

Device Group:
W02039085

BUDI-DI:
150995902UALAMINA39

Risk Class:
Class A, Rule 5 (Article 47 in accordance with Annex VIII)

Authorized Representative (AR)
N/A

AR SRN: N/A

Intended Purpose:
iQ Lamina is intended for in vitro diagnostic use with the iQ200 or DxU 840/850m Series of Automated Urine Microscopy Analyzers. It is used to hydrodynamically position the flow of specimen within the focal depth of the lens of the microscope and to ensure streamlined flow by rinsing and wetting all fluidic components. The device is intended to be used by a laboratory professional.

Common Specification(s):
None

Conformity Assessment Procedure:
Conformity Assessment based on a Quality Management System and on Technical Documentation in accordance with Annex II and III, and declaration of conformity in accordance with Article 17 and Annex IV.

Signed for and on behalf of Beckman Coulter Ireland, Inc. the Legal Manufacturer.

Name: Nery Ortiz 2022-07-06
Title: Sr. Manager Regulatory Affairs, PRRC
Place of Issue: Beckman Coulter, Inc., Miami, FL USA

Notified Body

N/A - Self Declared

Product Certificate Number: N/A

	Beckman Coulter Ireland, Inc. Lismeehan, O'Callaghan's Mills Co. Clare Ireland +(353) (0) 65 683 1100 **Manufacturer SRN:** IE-MF-000000887	**Document Control**	
		Issue Date: **Revision Level:** **Starting Lot:** **DoC Filename:**	2022-04-20 1.2 151-22M IRL-0095 DOC

Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produckte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listadoes a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name	Part Number (PN)
iChem VELOCITY Urine Chemistry Strips	800-7204

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General

GMDN Code(s):
54514

5th March 2021

Marie O'Rourke
Director Quality and Regulatory Affairs

Date

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level: 1.2
Revision Date:03/03/2021
Starting Lot #: 7204500M
Filename: 8007204DEC

DECLARATION OF CONFORMITY

Not classified as hazardous

SDS Safety Data Sheet is available at beckmancoulter.com/techdocs

Beckman Coulter Ireland Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the *In-Vitro* Diagnostic Medical Devices Regulation 2017/746.

This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Product(s):
iChemVELOCITY Wash Solution - PN 800-7217

Device Group:
W02039085

BUDI-DI:
150995902UAWASHSOLW6

Risk Class:
Class A, Rule 5 (Article 47 in accordance with Annex VIII)

Authorized Representative (AR)
N/A

AR SRN: N/A

Intended Purpose:
The iChemVELOCITY Wash Solution is a buffer solution for routine rinse of the iChemVELOCITY or DxU 810c Series of Automated Urine Chemistry Analyzers. This reagent is intended for in vitro diagnostic use with the iChemVELOCITY or DxU 810c Series of Automated Urine Chemistry Analyzers. It is a ready-for-use solution specifically developed for the application in the iChemVELOCITY or DxU 810c Series of Automated Urine Chemistry Analyzers. Use of this Wash Solution properly provides the optimal operating condition for the System. The device is intended to be used by a laboratory professional.

Common Specification(s):
None

Conformity Assessment Procedure:
Conformity Assessment based on a Quality Management System and on Technical Documentation in accordance with Annex II and III, and declaration of conformity in accordance with Article 17 and Annex IV.

Signed for and on behalf of Beckman Coulter Ireland, Inc. the Legal Manufacturer.

Name: Nery Ortiz 2022-07-06
Title: Sr. Manager Regulatory Affairs, PRRC
Place of Issue: Beckman Coulter, Inc., Miami, FL USA

Notified Body

N/A - Self Declared

Product Certificate Number: N/A

	Beckman Coulter Ireland, Inc. Lismeehan, O'Callaghan's Mills Co. Clare Ireland +(353) (0) 65 683 1100 **Manufacturer SRN:** IE-MF-000000887	**Document Control**	
		Issue Date: **Revision Level:** **Starting :** **DoC Filename:**	2022-04-26 1.2 April 27th, 2022 IRL-0099 DOC

Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produckte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listadoes a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name	Part Number (PN)
iChemVELOCITY CalChek Kit	800-7703

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General IVD (non Annex II, non self test)

GMDN Code(s):
30219

Nery Ortiz
Sr. Manager Regulatory Affairs

07 Feb 2019
Date

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level:1.0
Revision Date:12/14/2018
Starting Lot #: N/A
Filename: 8007703DEC

Declaration of Conformity

Beckman Coulter Ireland, Inc. hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.

Beckman Coulter Ireland, Inc. assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland, Inc dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland, Inc versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produckte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland, Inc asegura y declara que los productos listadoes a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product Name	Part Number (PN)
IRISpec CA/CB/CC	800-7702

Conformity Assessment Procedure
Annex III –Self-declared

Classification:
General IVD (non Annex II, non self test)

GMDN Code(s):

30219

Nery Ortiz
Sr. Manager Regulatory Affairs

07 Feb 2019
Date

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Co. Clare, Ireland

Document Control
Issue Date: 12/14/2018
Revision Level:1.0
Revision Date:12/14/2018
Starting Lot #: N/A
Filename: 8007702DEC

Declaration of Conformity

***Beckman Coulter Ireland Inc.,* hereby ensures and declares that the product(s) listed below comply with the requirement of the European Union In-vitro Diagnostics Medical Device Directive 98/79/EC.**

Beckman Coulter Ireland Inc., assure et déclare par la présente que le(s) produit(s) listé(s) ci-dessous sont conformes aux exigences de la directive européenne 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro.

Beckman Coulter Ireland Inc., dichiara ed assicura che i prodotti qui elencati sono conformi ai requisiti della direttiva comunitaria 98/79/CE relativa ai dispositivi medico-diagnostici in vitro.

Beckman Coulter Ireland Inc., versichert und erklärt hiermit, daß die im Folgenden aufgeführten Produckte den Auflagen der IVD-Richtlinie für In-vitro-Diagnostika der Europäischen Union (98/79/EC) entsprechen.

Beckman Coulter Ireland Inc., asegura y declara que los productos listadoes a continuación cumplen con los requisitos establecidos en la directiva 98/79/EC de la Comunidad Europea para dispositivos médicos de diagnóstico in vitro.

Product(s) /Produkt(e) /Prodotto(i) / Produit(s) / Producto(s):

Product	Part Number	Instrument Part Number	GMDN Code
Stand Alone iChemVELOCITY (Int'l)	800-7100	B75503	35918
iChem® VELOCITY™ Back Integrated (Int'l)	800-7103	B75502	35918
iChemVELOCITY, Back Integrated w/o Bridge (Int'l)	800-7162	B75502	35918
iChem® VELOCITY™ StandAlone W/Racks 1-18 (Int'l)	800-7163	B75502	35918
iChem® VELOCITY™ w/ Load/Unload (Int'l)	800-7166	B75502	35918
iChemVELOCITY Computerless System (Int'l)	800-3564	B75502	35918
iChem®VELOCITY™ Dessicant Kit	B79319	N/A	35918
UA WIN10 Kit	C52900	N/A	35918
iQ200 Series Software version 8.0	C50833	N/A	35918

Standard(s) / Norm(en) / Norma(e) / Norme(s) / Norma(s):

EMC:	IEC/EN61326-1:2013 IEC/EN61326-2-6:2013
Product Safety:	IEC61010-1:2001 IEC61010-2-081:2001 IEC61010-2-101:2002
RoHS:	BS EN 50581:2012

Conformity Assessment Procedure
Annex III, Self-Declared
CE MARK Affixed

Classification:
General IVD

Notified Body
N/A

Document Control
Issue Date: 05/08/2020
Revision Level: 2.3
Revision Date: 08-May-2020
Starting serial #: V04225
RoHS Serial #: V05000
Filename: 2.8.3.10

Samy Puccio
Senior Manager, Regulatory Affairs

11 May 2020
Date

Beckman Coulter Ireland Inc.
Lismeehan
O'Callaghan's Mills
Clare
Ireland