

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Agilent Technologies Singapore (International) Pte Ltd. No. 1 Yishun Avenue 7 Singapore, 768923	
European Representative:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Manufacturing Site:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Product:	Polyclonal Rabbit Anti-Human IgD	
Code:	A0093	
Classification:	<input type="checkbox"/> Annex II, List B <input checked="" type="checkbox"/> Self-Declaration	
Conformity Assessment Route:	<input type="checkbox"/> Annex IV <input checked="" type="checkbox"/> Annex III	
GMDN Code and Product Term:	57312 Total immunoglobulin D (IgD total) IVD, antibody	
<p>This declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above-mentioned product meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.</p> <p>This declaration is based upon a review that the specific requirements concerning:</p> <ol style="list-style-type: none"> 1. The preparation of the required technical documentation; 2. The implementation of the specified principles of quality assurance, and; 3. The implementation of a systematic procedure for Post-Market Vigilance and Surveillance; <p>have been satisfactorily fulfilled and that the product is not intended for self-testing.</p>		
List of Harmonised Standards used in full or part:	<ul style="list-style-type: none"> • EN ISO 13485 • EN ISO 14971 • EN ISO 18113-1 • EN ISO 18113-2 • EN ISO 15223-1 • EN ISO 23640 • EN ISO 62366-1 	
Notified Body:	(Applies only for Annex II, List B products)	
(EC) Certificate:	(Applies only for Annex II, List B products)	
Place:	Glostrup, Denmark	
Signed for and on the behalf of Agilent Technologies Singapore (International) Pte Ltd.	Name: Lars Hansen	
Signature:	Position: Senior RA Specialist	
	Date: 2020DEC01	

Not subject to issue control when printed

	EC Declaration of Conformity	Page 1 of 3
		Document Number/Rev:D32759/09
	Document Type: Template	Effective Date: See ECO C84746
		Project Name/No: (If relevant)

This document must be created in Agile as document type: Product Development and Category: Regulatory Documentation and receive a D-number.

Responsibility & Approvals:

For signature see electronic records in Agile or appended electronic signature page.

Regulatory Affairs	Yann Cailler
Quality Assurance or Regulatory Affairs	Konstantinos Papacharalampos

Template Title: EC Declaration of Conformity
Template Number / Rev: QX114/25
Effective Date: See ECO C69636

Confidential
Master: Template_For_Templates Rev: 06

EC DECLARATION OF CONFORMITY

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European Representative:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Manufacturing site:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Product: Code:	Monoclonal Mouse Anti-Human Prostate-Specific Antigen Clone ER-PR8 M0750	
Classification:	<input checked="" type="checkbox"/> Annex II, List B <input type="checkbox"/> Self-Declaration	
Conformity Assessment Route:	<input checked="" type="checkbox"/> Annex IV <input type="checkbox"/> Annex III	
GMDN Code and Product Term:	63066 Free (unbound) prostate specific antigen (PSA) IVD, antibody	
<p>This declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above-mentioned product meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.</p> <p>This declaration is based upon a review that the specific requirements concerning:</p> <ol style="list-style-type: none"> 1. The preparation of the required technical documentation; 2. The implementation of the specified principles of quality assurance, and; 3. The implementation of a systematic procedure for Post-Market Vigilance and Surveillance; <p>have been satisfactorily fulfilled and that the product is not intended for self-testing.</p>		
List of Harmonised Standards used in full or part:	<ul style="list-style-type: none"> • EN ISO 13485 • EN ISO 14971 • EN ISO 18113-2 • EN ISO 15223-1 • EN ISO 23640 	
Notified Body:	<p>(Applies only for Annex II, List B products)</p> <p>Polish Centre for Testing and Certification 469 Puławska Street 02-844 Warszawa Poland Notified Body no. 1434</p>	
(EC) Certificate:	<p>(Applies only for Annex II, List B products)</p> <p>EC Certificate No. 1434-IVDD-130/2022</p>	
Place:	Glostrup, Denmark	
Signature (International) Signature	Agilent Technologies Singapore	<p>Name: Yann Cailler</p> <p>Position: Regulatory Affairs, Manager</p> <p>Date: 2023MAY25</p>

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Agilent Technologies, Inc. 5301 Stevens Creek Blvd. Santa Clara, CA 95051 United States	
European Representative:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Manufacturing site:	Agilent Technologies, Inc. 6392 Via Real Carpinteria, CA 93013 United States	
Product: Code:	Monoclonal Mouse Anti-Human Androgen Receptor, Clone AR441 M3562	
Classification:	<input type="checkbox"/> Annex II, List B <input checked="" type="checkbox"/> Self-Declaration	
Conformity Assessment Route:	<input type="checkbox"/> Annex IV <input checked="" type="checkbox"/> Annex III	
GMDN Code and Product Term:	56796 - androgen receptor IVD, antibody	
<p>This declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above-mentioned product meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.</p> <p>This declaration is based upon a review that the specific requirements concerning:</p> <ol style="list-style-type: none"> 1. The preparation of the required technical documentation; 2. The implementation of the specified principles of quality assurance, and; 3. The implementation of a systematic procedure for Post-Market Vigilance and Surveillance; <p>have been satisfactorily fulfilled and that the product is not intended for self-testing.</p>		
List of Harmonised Standards used in full or part:	<ul style="list-style-type: none"> • EN ISO 13485 • EN ISO 14971 • EN ISO 18113-2 • EN ISO 15223-1 	
Notified Body:	(Applies only for Annex II, List B products)	
(EC) Certificate:	(Applies only for Annex II, List B products)	
Place:	Carpinteria, USA	
Signed for and on the behalf of Agilent Technologies, Inc. Signature:	Name: Joel Weisenberger Position: Manager, Regulatory Affairs Date: 2020NOV25	

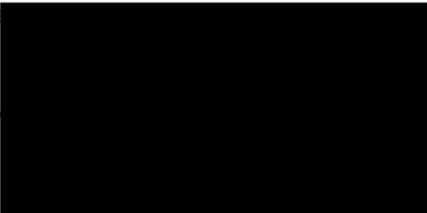
EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Agilent Technologies Singapore (International) Pte Ltd. No. 1 Yishun Avenue 7 Singapore, 768923
European Representative:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark
Manufacturing Site:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark
Product: Code:	Monoclonal Mouse Anti-Human Epithelial Membrane Antigen, Clone E29 M0613
Classification:	<input type="checkbox"/> Annex II, List B <input checked="" type="checkbox"/> Self-Declaration
Conformity Assessment Route:	<input type="checkbox"/> Annex IV <input checked="" type="checkbox"/> Annex III
GMDN Code and Product Term:	57195 Epithelial membrane antigen (EMA) IVD, antibody
<p>This declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above-mentioned product meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.</p> <p>This declaration is based upon a review that the specific requirements concerning:</p> <ol style="list-style-type: none"> 1. The preparation of the required technical documentation; 2. The implementation of the specified principles of quality assurance, and; 3. The implementation of a systematic procedure for Post-Market Vigilance and Surveillance; <p>have been satisfactorily fulfilled and that the product is not intended for self-testing.</p>	
List of Harmonised Standards used in full or part:	<ul style="list-style-type: none"> • EN ISO 13485 • EN ISO 14971 • EN ISO 18113-2 • EN ISO 15223-1 • EN ISO 23640
Notified Body:	(Applies only for Annex II, List B products)
(EC) Certificate:	(Applies only for Annex II, List B products)
Place:	Glostrup, Denmark
Signed for and on the behalf of Agilent Technologies Singapore (International) Pte L Signature:	<p>Name: Lars Hansen</p> <p>Position: Senior RA Specialist</p> <p>Date: 2020DEC01</p>

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Agilent Technologies Singapore (International) Pte Ltd. No. 1 Yishun Avenue 7 Singapore, 768923	
European Representative:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Manufacturing Site:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Product: Code:	Monoclonal Mouse Anti-Human CD45, Leucocyte Common Antigen, Clones 2B11 + PD7/26 M0701	
Classification:	<input type="checkbox"/> Annex II, List B <input checked="" type="checkbox"/> Self-Declaration	
Conformity Assessment Route:	<input type="checkbox"/> Annex IV <input checked="" type="checkbox"/> Annex III	
GMDN Code and Product Term:	56988 CD45 leukocyte common antigen cell marker IVD, antibody	
<p>This declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above-mentioned product meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.</p> <p>This declaration is based upon a review that the specific requirements concerning:</p> <ol style="list-style-type: none"> 1. The preparation of the required technical documentation; 2. The implementation of the specified principles of quality assurance, and; 3. The implementation of a systematic procedure for Post-Market Vigilance and Surveillance; <p>have been satisfactorily fulfilled and that the product is not intended for self-testing.</p>		
List of Harmonised Standards used in full or part:	<ul style="list-style-type: none"> • EN ISO 13485 • EN ISO 14971 • EN ISO 18113-2 • EN ISO 15223-1 • EN ISO 23640 	
Notified Body:	(Applies only for Annex II, List B products)	
(EC) Certificate:	(Applies only for Annex II, List B products)	
Place:	Glostrup, Denmark	
Signed for and on the behalf of Agilent Technologies Singapore (International) Pte Ltd.	Name:	Lars Hansen
Signature:	Position:	Senior RA Specialist
	Date:	2020DEC01

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Agilent Technologies Singapore (International) Pte Ltd. No. 1 Yishun Avenue 7 Singapore, 768923	
European Representative:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Manufacturing Site:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Product: Code:	Monoclonal Mouse Anti-Human CD21, Clone 1F8 M0784	
Classification:	<input type="checkbox"/> Annex II, List B <input checked="" type="checkbox"/> Self-Declaration	
Conformity Assessment Route:	<input type="checkbox"/> Annex IV <input checked="" type="checkbox"/> Annex III	
GMDN Code and Product Term:	56956 CD21 cell marker IVD, antibody	
<p>This declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above-mentioned product meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.</p> <p>This declaration is based upon a review that the specific requirements concerning:</p> <ol style="list-style-type: none"> 1. The preparation of the required technical documentation; 2. The implementation of the specified principles of quality assurance, and; 3. The implementation of a systematic procedure for Post-Market Vigilance and Surveillance; <p>have been satisfactorily fulfilled and that the product is not intended for self-testing.</p>		
List of Harmonised Standards used in full or part:	<ul style="list-style-type: none"> • EN ISO 13485 • EN ISO 14971 • EN ISO 18113-2 • EN ISO 15223-1 • EN ISO 23640 	
Notified Body:	(Applies only for Annex II, List B products)	
(EC) Certificate:	(Applies only for Annex II, List B products)	
Place:	Glostrup, Denmark	
Signed for and on the behalf of Agilent Technologies Singapore (International) Pte Ltd.	Name:	Lars Hansen
Signature: 	Position:	Senior RA Specialist
	Date:	2020DEC01

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Agilent Technologies Singapore (International) Pte Ltd. No. 1 Yishun Avenue 7 Singapore, 768923	
European Representative:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Manufacturing Site:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Product: Code:	Monoclonal Mouse Anti-Human Cytokeratin 20, Clone Ks20.8 M7019	
Classification:	<input type="checkbox"/> Annex II, List B <input checked="" type="checkbox"/> Self-Declaration	
Conformity Assessment Route:	<input type="checkbox"/> Annex IV <input checked="" type="checkbox"/> Annex III	
GMDN Code and Product Term:	57079 Cytokeratin IVD, antibody	
<p>This declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above-mentioned product meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.</p> <p>This declaration is based upon a review that the specific requirements concerning:</p> <ol style="list-style-type: none"> 1. The preparation of the required technical documentation; 2. The implementation of the specified principles of quality assurance, and; 3. The implementation of a systematic procedure for Post-Market Vigilance and Surveillance; <p>have been satisfactorily fulfilled and that the product is not intended for self-testing.</p>		
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Notified Body:	(Applies only for Annex II, List B products)	
(EC) Certificate:	(Applies only for Annex II, List B products)	
Place:	Glostrup, Denmark	
Signed for and on the behalf of Agilent Technologies Singapore (International) Pte Ltd Signature:	Name: Lars Hansen Position: Senior RA Specialist Date: 2020DEC01	

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Agilent Technologies Singapore (International) Pte Ltd. No. 1 Yishun Avenue 7 Singapore, 768923	
European Representative:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Manufacturing Site:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Product:	Monoclonal Mouse Anti-Human CD79α, Clone JCB117	
Code:	M7050	
Classification:	<input type="checkbox"/> Annex II, List B <input checked="" type="checkbox"/> Self-Declaration	
Conformity Assessment Route:	<input type="checkbox"/> Annex IV <input checked="" type="checkbox"/> Annex III	
GMDN Code and Product Term:	57018 CD79a cell marker IVD, antibody	
<p>This declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above-mentioned product meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.</p> <p>This declaration is based upon a review that the specific requirements concerning:</p> <ol style="list-style-type: none"> 1. The preparation of the required technical documentation; 2. The implementation of the specified principles of quality assurance, and; 3. The implementation of a systematic procedure for Post-Market Vigilance and Surveillance; <p>have been satisfactorily fulfilled and that the product is not intended for self-testing.</p>		
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Notified Body:	(Applies only for Annex II, List B products)	
(EC) Certificate:	(Applies only for Annex II, List B products)	
Place:	Glostrup, Denmark	
Signed for and on the behalf of Agilent Technologies Singapore (International) Pte Ltd.	Name:	Lars Hansen
Signature:	Position:	Senior RA Specialist
	Date:	2020DEC01



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Legal Manufacturer:	Agilent Technologies Singapore (International) Pte Ltd. No. 1 Yishun Avenue 7 Singapore, 768923	
European Representative:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Manufacturing Site:	Agilent Technologies Denmark ApS Produktionsvej 42 DK-2600 Glostrup Denmark	
Product: Code:	Monoclonal Mouse Anti-Human Ki-67 Antigen, Clone MIB-1 M7240	
Classification:	<input type="checkbox"/> Annex II, List B <input checked="" type="checkbox"/> Self-Declaration	
Conformity Assessment Route:	<input type="checkbox"/> Annex IV <input checked="" type="checkbox"/> Annex III	
GMDN Code and Product Term:	57338 Ki67 antigen IVD, antibody	
<p>This declaration of conformity is issued under the sole responsibility of the manufacturer. We herewith declare that the above-mentioned product meets the provisions of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices. All supporting documentation is retained at the premises of the manufacturer.</p> <p>This declaration is based upon a review that the specific requirements concerning:</p> <ol style="list-style-type: none"> 1. The preparation of the required technical documentation; 2. The implementation of the specified principles of quality assurance, and; 3. The implementation of a systematic procedure for Post-Market Vigilance and Surveillance; <p>have been satisfactorily fulfilled and that the product is not intended for self-testing.</p>		
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Notified Body:	(Applies only for Annex II, List B products)	
(EC) Certificate:	(Applies only for Annex II, List B products)	
Place:	Glostrup, Denmark	
Signed for and on the behalf of Agilent Technologies Singapore (International) Pte Ltd. Signature:	Name: Lars Hansen Position: Senior RA Specialist Date: 2020DEC01	

EU DECLARATION OF CONFORMITY

	<p>Agilent Technologies, Inc. 5301 Stevens Creek Blvd. Santa Clara, California, 95051 United States</p>		
SRN	US-MF-000009385		
<table border="1" style="display: inline-table; border-collapse: collapse;"> <tr> <td style="padding: 2px;">EC</td> <td style="padding: 2px;">REP</td> </tr> </table>	EC	REP	<p>Agilent Technologies Denmark ApS Produktionsvej 42 2600 Glostrup Denmark</p>
EC	REP		
SRN	DK-AR-000001443		
Manufacturing Site Name & Address	<p>Agilent Technologies, Inc. 1170 Mark Ave. Carpinteria, California 93013 United States</p>		
Basic UDI-DI	570057P3007P3010A053901PK		
Product name	Dako Faramount Aqueous Mounting Medium, Ready-to-use		
REF	S3025		
EMDN Code	W01030706		
Risk Class	<input checked="" type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C <input type="checkbox"/> D		
Conformity Assessment Route:	<p><input type="checkbox"/> ANNEX IX Quality Management System and assessment of technical documentation, section 4</p> <p><input type="checkbox"/> ANNEX IX Quality Management System and assessment of technical documentation, section 4 and 5.2</p> <p><input checked="" type="checkbox"/> ANNEX II+III (non-sterile class A, self declaration)</p>		
Notified Body:	<input checked="" type="checkbox"/> Not applicable to non-sterile Class A product		
(EC) Certificate #:	<input checked="" type="checkbox"/> Not applicable to non-sterile Class A product		
<p>We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives</p>			
<p>Regulation EU 2017/746 on <i>In vitro</i> Diagnostic Medical Devices</p>			
Common Specifications and Standards used in full or part:	<ul style="list-style-type: none"> • EN ISO 13485:2016 + A11:2021 • EN ISO 14971:2019 • EN 13641:2002 • EN ISO 18113-1:2011 • EN ISO 18113-2:2011 • EN ISO 15223-1:2021 • EN ISO 23640:2015 • EN 62366-1:2015 + AC:2015+AC:2016+A1:2020 • ISO 20417:2021 		

Joel Weisenberger



Agilent



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Glossary

EN	EU DECLARATION OF CONFORMITY	SRN	Manufacturing Site Name & Address	Basic UDI-DI	Product name	EMDN code	Risk Class	Conformity Assessment Route	ANNEX IX Quality Management System and assessment of technical documentation, section 4	ANNEX IX Quality Management System and assessment of technical documentation, section 4 and 5.2
ANNEX II+III	Notified Body (EC) Certificate #	Not applicable to non-sterile Class A product	W/o as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directive: Regulation (EU) 2017/746 on in vitro diagnostic medical devices					Common Specifications and Standards used in full or part		Glossary
BG	ЕС ДЕКЛАРАЦИЯ ЗА СЪОТВЕТСТВИЕ	Единичен регистрационен номер	Име и адрес на произвождателя	Основан UDI-DI	Име на продукта	EMDN код	Клас на риска	Метод за оценяване на съответствието	Система за управление на качеството и оценя на техническата документация, раздел 4 и 5.2	Управление на качеството и оценя на техническата документация, раздел 4 и 5.2
TR	ТРПЛОЖЕНИЕ	Нотифициран орган II + III	№ на сертификат (на EO)							Речник
CS	EU PROHLÁŠENÍ O SHODĚ	SRN	Název a adresa výrobního závodu	Základní UDI-DI	Název produktu	Kód EMDN	Třída rizika	Cesta posouzení shody	PRILLOHA IX System řízení kvality a posouzení technické dokumentace, část 4	PRILLOHA IX System řízení kvality a posouzení technické dokumentace, část 4 a 5.2
PT	PRÉLONA II+III	Notificada osoba	Certificado t.							Glossar
DA	EU-OVERENSSTEMMELSESERKLÆRING	SRN	Navn og adresse på produktionsstedet	Grundlæggende UDI-DI	Produktnavn	EMDN-kode	Risikoklasse	Overensstemmelsesvurderingsvej	BILAG IX Kvalitetssystem og vurdering af teknisk dokumentation, afsnit 4 og 5.2	BILAG IX Kvalitetssystem og vurdering af teknisk dokumentation, afsnit 4 og 5.2
BLAG II+III	Bemyndiget organ	(EU) Certificatnr.	Gælder ikke for ikke-sterile produkter i klasse A							Ordliste
DE	EUKONFORMITÄTSERKÄRUNG	SRN	Name und Adresse Herstellungsstandorts	Basiz-UDI-DI	Produktbezeichnung	EMDN-Code	Risikoklasse	Prüf für Konformitätsbewertung	ANHANG IX Qualitätsmanagementsystem und Bewertung der technischen Dokumentation, Abschnitt 4	ANHANG IX Qualitätsmanagementsystem und Bewertung der technischen Dokumentation, Abschnitte 4 und 5.2
ANHANGE II+III	Notifizierte Stelle	(EC-) Zertifikatsnr.	Nicht anwendbar für nicht sterile Produkte der Klasse A							Glossar
EL	ΔΗΛΩΣΗ ΣΥΜΜΟΡΦΩΣΗΣ ΕΕ	SRN	Όνομα και διεύθυνση κέντρου κατασκευής	Βασικό UDI-DI	Όνομα προϊόντος	Κωδικός EMDN	Κατηγορία κινδύνου	Διαδικασία αξιολόγησης συμμόρφωσης	ΑΠΡΟΒΛΗΤΑ ΙΧ Σύστημα διαχείρισης ποιότητας και αξιολόγησης τεχνικής τεκμηρίωσης, παράρτημα 4 και 5.2	Πρόσθετο διαχείρισης ποιότητας και αξιολόγησης τεχνικής τεκμηρίωσης, παράρτημα 4 και 5.2
ΠΑΡΑΡΤΗΜΑ II+III	Κοινοποιημένος οργανισμός	(ΕΚ) Αρ. πιστοποίησης	Δεν ισχύει για μη στείρα προϊόντα Κλάσης Α							Πρόσθετο
ES	DECLARACIÓN DE CONFORMIDAD DE LA UE	N.º DE REGISTRO UNICO	Nombre y dirección del centro de fabricación	UDI-DI básico	Nombre del producto	Código EMDN	Clase de riesgo	Regla de evaluación de la conformidad	ANEEXO IX Sistema de gestión de la calidad y evaluación de la documentación técnica, apartado 4	ANEEXO IX Sistema de gestión de la calidad y evaluación de la documentación técnica, apartados 4 y 5.2
ANEEXO II+III	Organismo notificado	(EC) N.º de certificado	No se aplica a los productos de clase A no estériles							Glossario
ET	EU VASTAVUSEKLAATSIIOON	Unikaalne registreerimisnumber	Tööstuskohta nimi ja aadress	Põhi-UDI-DI	Toota nimetus	EMDN-kood	Riskiklass	Vastavushindamise põhimõtte	USA IX Kvaliteedihindamise süsteemi ja tehnilise dokumentatsiooni hindamine, punkt 4	USA IX Kvaliteedihindamise süsteemi ja tehnilise dokumentatsiooni hindamine, punkt 4 ja 5.2
USA II+III	Taavitud asutus	(EU) sertifikaat #	Ei kohaldata A-klassi mitesteriliste toodete suhtes							Mõistet
			Mete, seadmete) tootja, vastutame ainsuskitsuse eespool nimetatud tootekoode eest ja kinnitame, et eespool nimetatud toodetud vastavalt järgmistele määrusdirektiivide sätetele: Määrus (EU) 2017/746 meditsiiniliste in vitro diagnostikavahendite kohta							

FI	EU-VAAKTIIVISTENMIUKAISUUSVAKUUTUS	SRN	Valmistuspaikan nimi ja osoite	Yksilöllinen UDI-DI-tunniste	Tuotem nimi	EMDN-koodi	Riskiluokka	Vaaratilustienmukaisuuden arviointitiet	LITTE IX Laadunhallintajärjestelmä ja teknisten asiakirjojen arvointi, luvut 4	LITTE IX Laadunhallintajärjestelmä ja teknisten asiakirjojen arvointi, luvut 4 ja 5.2
LITTEET II + III	Limoleittu laitos (EY) todistusnro luoteita									
FR	DECLARATION DE CONFORMITE UE	N° d'identification unique	Nom et adresse du site de fabrication	UDI-DI de base	Nom du produit	Réf. EMDN	Classe de risque	Procédure d'évaluation de la conformité	ANNEXE IX – Système de gestion de la qualité et évaluation de la documentation technique, section 4	ANNEXE IX – Système de gestion de la qualité et évaluation de la documentation technique, sections 4 et 5.2
ANNEXES II+III	Organisme notifié	N° de certificat (CE)	Ne s'applique pas aux produits non stériles de classe A		En notre qualité de fabricant du ou des dispositifs, nous assumons l'entière responsabilité et déclarons par la présente que le ou les produits mentionnés ci-dessus sont conformes aux dispositions des règlements/directives suivants. Règlement (UE) 2017/746 relatif aux dispositifs médicaux de diagnostic in vitro			Specifications et normes communes utilisées en totalité ou en partie	Glossaire	Glossaire
HR	EU IZJAVA O SUKLADNOSTI	Jedinstveni registracijski broj	Naziv i adresa njezina proizvodnje	Osnovni UDI-DI broj	Naziv proizvoda	EMDN kod	Klasa rizika	Slijed progone sukladnosti	DODATAK IX Sustav za upravljanje kvalitetom i procjena tehničke dokumentacije, odjelci 4 i 5.2	DODATAK IX Sustav za upravljanje kvalitetom i procjena tehničke dokumentacije, odjelci 4 i 5.2
DODATAK II+III	Prijavljeno tijelo certifikata	Broj (EC) certifikata	Ne vrijedi za nesterilne proizvode klase A		Mi, kao proizvođač proizvoda, isključivo smo odgovorni i izjavljujemo da gore navedeni proizvod zadovoljava odredbe slijedećih regulativnih dokumenata: Uredba (EU) 2017/746 o in vitro dijagnostičkim medicinskim proizvodima			Opće specifikacije i norme upotrijebljene djelomično ili u potpunosti	Pojmovnik	Pojmovnik
HU	EU-VEGFELŐSEGI NYILATKOZAT	Egyedi regisztrációs szám (SRN):	Gyártási hely neve és címe	Alapvető UDI-DI	Terméknév	EMDN-kód	Kockázati osztály	Megfelelőségértékelési mód	IX. MELLÉKLET A Minőségirányítási rendszer és a műszaki dokumentáció vizsgálata, 4. bekezdés	IX. MELLÉKLET A Minőségirányítási rendszer és a műszaki dokumentáció vizsgálata, 4. és 5.2. bekezdés Szószedet
II+III	Ertesített szerv	(EK) tanúsítvány száma	Az asztal Class A (A osztályú) terméknek esetenként nem alkalmazható		Norme del prodotto	Codice EMDN	Classe di rischio	Procedura di valutazione della conformità	ALLEGATO IX Sistema di gestione della qualità e valutazione della documentazione tecnica, sezione 4	ALLEGATO IX Sistema di gestione della qualità e valutazione della documentazione tecnica, sezioni 4 e 5.2
IT	DICHIARAZIONE DI CONFORMITÀ UE	Numero di registrazione unico	Norme e indirizzo del sito di produzione	UDI-DI di base	Nome del prodotto	EMDN	Rischio	Procedura di valutazione della conformità	ALLEGATO IX Sistema di gestione della qualità e valutazione della documentazione tecnica, sezioni 4 e 5.2	ALLEGATO IX Sistema di gestione della qualità e valutazione della documentazione tecnica, sezioni 4 e 5.2
ALLEGATI II+III	Organismo notificato	N. certificato (CE)	Non applicabile ai prodotti non sterili di classe A		In qualità di fabbricanti dei dispositivi, ci assumiamo la responsabilità esclusiva per tale dispositivo e con la presente dichiariamo che il suddetto prodotto soddisfa le disposizioni previste dai seguenti regolamenti/direttive: Regolamento (UE) 2017/746 relativo ai dispositivi medico-diagnostici in vitro			Norme e specifiche comuni applicate in tutto o in parte:	Glossario	Glossario
LV	ES ATBILSTĪBAS DEKLARĀCIJA	SRN	Ražošanas vietas nosaukums un adrese	Pamata UDI-DI	Produkta nosaukums	EMDN kods	Riska kategorija	Audstības novērtēšanas ceļš	IX. PIELIKUMS Kvalitātes vadības sistēma ir tehniskās dokumentācijas novērtēšana, 4. un 5.2. iedaļa	IX. PIELIKUMS Kvalitātes vadības sistēma ir tehniskās dokumentācijas novērtēšana, 4. un 5.2. iedaļa
II+III	Paziņota struktūra	(EK) sertifikāts #	Neattiecas uz nesterili A klases produkti		Mēs kā ierīču (-u) ražotājus uzņemamies pilnīgu atbildību par paziņojam, ka ierīcēs (ies) (ies) atbilst turpmāk norādīto regulatīvo noteikumu: Regula (ES) 2017/746 par in vitro diagnostiskām medicīniskām ierīcēm			Kopēļas specifikaģijas un standarti, ko izmanto plimba vai daģij:	Vārduroc	Vārduroc
LT	ES ATTIKTIĖS DEKLARACIJA	SRN	Gamybos vietos pavadinimas ir adresas	Bazinis UDI-DI	Gaminio pavadinimas	EMDN kodas	Rizikos klasė	Atitikties vertinimo būdas	IX PRIEDAS Kokybės valdymo sistema ir techninių dokumentų vertinimas, 4 skirsnis	IX PRIEDAS Kokybės valdymo sistema ir techninių dokumentų vertinimas, 4 ir 5.2 skirsniai
II IR III PRIEDA	Notifikuoja įstaiga	(EB) sertifikato Nr.	Netaikoma nesteriliems A klasės produktams		Mes, prietaisų gamintojai, prisiimame visą atsakomybę pareiškime, kad aukščiau išvardinti produktai atitinka toliau nurodytų reglamentų / direktyvų nuostatas: Reglamentas (ES) 2017/746 dėl in vitro diagnostikos medicinos prietaisų			Visa apimtimi arba iš dalies taikomos bendrosios specifikacijos ir standartai:	Zodyvėlis	Zodyvėlis
NL	EU-conformiteitsverklaring	SRN	Naam en adres productlocatie	Basis-UDI-DI	Productnaam	EMDN-code	Risicoklasse	Conformiteitsbeoordelingsroute	BILAGGE IX Kvalitetsstyringsystemet og dokumentation, sektion 4	BILAGGE IX Kvalitetsstyringsystemet og dokumentation, sektion 4
BILAGGE I + III	Aangemelde instantie	(EC) Certificatnummer	Niet van toepassing op niet-steriel Klasse A-product		Wij, als fabrikant van het hulpmiddel/de hulpmiddelen nemen de volledige verantwoordelijkheid voor en verklaren hierbij dat het hierboven genoemde product voldoet/de hierboven genoemde producten voldoen aan de volgende verordening/directieven: Verordening (EU) 2017/746 betrefft in vitro diagnostische medische hulpmiddelen			Gemeenschappelijke specificaties en normen, volledig of deels gebruikt:	Begripverlijst	Begripverlijst
PL	DEKLARACJA ZGODNOŚCI UE	Numer SRN	Nazwa i adres zakładu produkcyjnego	Kod Basic UDI-DI	Nazwa produktu	Kod EMDN	Klasa ryzyka	Soczeka oceny zgodności	ZALĄCZNIK IX System zarządzania jakością i ocena dokumentacji technicznej, punkty 4 i 5.2	ZALĄCZNIK IX System zarządzania jakością i ocena dokumentacji technicznej, punkty 4 i 5.2
ZALĄCZNIK II+III	Jednostka notyfikowana	Numer certyfikatu (WE)	Nie dotyczy nesterylnych produktów klasy A		Mi, jako producent wyrobów (wyrobów), bierzemy na siebie wyłączną odpowiedzialność i niniejszym oświadczamy, że wyżej wymieniony produkt (produkty) spełnia (spełniają) postanowienia następujących rozporządzeń/direktyw: Rozporządzenie (UE) 2017/746 w sprawie wyrobów medycznych do diagnostyki in vitro			Wspólne specyfikacje i normy stosowane w całości lub częściowo:	Glossarusz	Glossarusz

