



Parc Technologique Léonard de Vinci - Rue Léonard de Vinci – CP 8010 LISSES
91008 EVRY CEDEX (FRANCE)

Déclaration de conformité CE
EC conformity declaration

DISPOSITIFS MEDICAUX DE DIAGNOSTIC IN VITRO
DIRECTIVE 98/79/CE

IN VITRO DIAGNOSTIC MEDICAL DEVICES
DIRECTIVE 98/79/EC

Nous certifions que le dispositif HYDRAGEL 15 B1-B2 (référence 4121), ayant la classification « autre dispositif » (non listé dans l'Annexe II) selon la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE, remplit toutes les exigences de cette directive qui le concernent, notamment il répond aux exigences des Annexes I et III.

We certify that the device HYDRAGEL 15 B1-B2 (reference 4121), classified as "other device" (not listed in Annex II) according to the directive on in vitro diagnostic medical devices 98/79/EC, meets all the provisions of this directive which apply to it, particularly it answers to the exigencies of the Annex I and III.

Lisses, le 5 septembre 2011

B. Adelus
President



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Nous certifions que le dispositif SÉRUM DE CONTRÔLE NORMAL (5) (référence 4785), ayant la classification « autre dispositif » (non listé dans l'Annexe II) selon la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE, remplit toutes les exigences de cette directive qui le concernent, notamment il répond aux exigences des Annexes I et III.

We certify that the device NORMAL CONTROL (5) (reference 4785), classified as "other device" (not listed in Annex II) according to the directive on in vitro diagnostic medical devices 98/79/EC, meets all the provisions of this directive which apply to it, particularly it answers to the exigencies of the Annex I and III.

Lisses, le 5 septembre 2011

B. Adelus
President



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DIRECTIVE 98/79/EC

Nous certifions que le dispositif SÉRUM DE CONTRÔLE HYPERGAMMA (5) (référence 4787), ayant la classification « autre dispositif » (non listé dans l'Annexe II) selon la directive relative aux dispositifs médicaux de diagnostic in vitro 98/79/CE, remplit toutes les exigences de cette directive qui le concernent, notamment il répond aux exigences des Annexes I et III.

We certify that the device HYPERGAMMA CONTROL (5) (reference 4787), classified as "other device" (not listed in Annex II) according to the directive on in vitro diagnostic medical devices 98/79/EC, meets all the provisions of this directive which apply to it, particularly it answers to the exigencies of the Annex I and III.

Lisses, le 5 septembre 2011

B. Adelus
President

	EU DECLARATION OF CONFORMITY	Reference : ENR-AFR-05-2022-039 Indice : 01 Page : 1/1
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DESTAINING SOLUTION (10)	REF 4540	BUDI-DI: 3607364540BUDP
	Parc Technologique Léonard de Vinci CP 8010 LISSES – 91008 EVRY Cedex FRANCE	SRN: FR-MF-000003520

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:

- Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices.
 Directive 2011/65/UE on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

RISK CLASS

- A B C D

CONFORMITY ROUTE	EU CERTIFICATE #
<input type="checkbox"/> ANNEX IX Technical Documentation Examination (Class D, Near Patient and Self-testing devices).	Name of Notified Body: Notified Body Identification:
<input type="checkbox"/> ANNEX IX Quality Management System (Class B, C & D)	Name of Notified Body: Notified Body Identification:
<input type="checkbox"/> ANNEX X Type Examination (Class C & D)	Name of Notified Body: Notified Body Identification:
<input type="checkbox"/> ANNEX XI Production Quality System (Class C & D + sterile class A)	Name of Notified Body: Notified Body Identification:
<input checked="" type="checkbox"/> ANNEX I & II+III (non sterile class A)	

Common Specifications (CS) (if applicable):

Signature:

Issued Date:

25 May 2022



Name:

Arnaud COLLIN

Function:

Vice President Global Regulatory Affairs & Quality

	EU DECLARATION OF CONFORMITY	Reference : ENR-AFR-05-2022-039 Indice : 01 Page : 1/1
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HYDRASYS WASH SOLUTION (10)	REF 4541	BUDI-DI: 3607364541BUDU
	Parc Technologique Léonard de Vinci CP 8010 LISSES – 91008 EVRY Cedex FRANCE	SRN: FR-MF-000003520

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:

- Regulation EU 2017/746 on *In vitro* Diagnostic Medical Devices.
- Directive 2011/65/UE on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

RISK CLASS

- A B C D

CONFORMITY ROUTE	EU CERTIFICATE #
<input type="checkbox"/> ANNEX IX Technical Documentation Examination <i>(Class D, Near Patient and Self-testing devices).</i>	Name of Notified Body: Notified Body Identification:
<input type="checkbox"/> ANNEX IX Quality Management System <i>(Class B, C & D)</i>	Name of Notified Body: Notified Body Identification:
<input type="checkbox"/> ANNEX X Type Examination <i>(Class C & D)</i>	Name of Notified Body: Notified Body Identification:
<input type="checkbox"/> ANNEX XI Production Quality System <i>(Class C & D + sterile class A)</i>	Name of Notified Body: Notified Body Identification:
<input checked="" type="checkbox"/> ANNEX I & II+III <i>(non sterile class A)</i>	

Common Specifications (CS) (if applicable):

Signature:



Issued Date:

25 May 2022

Name:

Arnaud COLLIN

Function:

Vice President Global Regulatory Affairs & Quality