DECLARATION OF CONFORMITY

The undersigned Technogenetics S.p.A., with legal address at 1 Via Privata Cesare Battisti, 20122 Milano, and operation sites site at 24-26 Via Della Filanda, 26900 Lodi (LO), Italy, C.F. 06614040159, hereby declares under its own responsibility that, the in vitro diagnostic medical device:

- **CLIA KITS FOR INFECTIOUS DISEASE: BORRELIA,**

constituted by the items described here below:

Cat. N.	Name
IS-ID6201	IDS Borrelia IgG
IS-ID6202	IDS Borrelia IgM
IS-ID6230	IDS Borrelia - CONTROL SET

fulfils all the provisions listed in the Medical Device Directive 98/79/EC as amended.
Therefore, Technogenetics assures, under its own responsibility, that:

- "*CLIA kits for infectious disease: Borrelia*" are classified as in vitro diagnostic medical devices, which are not included in Annex II of 98/79/EC IVDD, and subsequent changes, and are not IVDs for performance evaluation;
- the above mentioned in vitro diagnostic medical devices satisfy the essential requirements in the Annex I of the national legislative regulations referring to 98/79/EC In Vitro Diagnostic Medical Device Directive and subsequent changes;

has followed the Conformity assessment procedure as per Annex III, except paragraph 6, because "*CLIA kits for infectious diseases: Borrelia*" are not IVDs for self-testing (according to 98/79/EC IVDD and subsequent changes);

prepare and keep available to the competent Authorities the technical documentation as specified in Annex III to the aforementioned directive for a period of at least five years from the date of production of the last batch.

Lodi, 04/01/2022

DECLARATION OF CONFORMITY

The undersigned Technogenetics S.p.A., with legal address at 1 Via Privata Cesare Battisti, 20122 Milano, and operation sites site at 24-26 Via Della Filanda, 26900 Lodi (LO), Italy, C.F. 06614040159, manufacturer of the in vitro diagnostic medical device ***CLIA KITS FOR INFECTIOUS DISEASES (Type C): TOXOPLASMOSIS,*** constituted by the items described here below:

Cat. N.	**Name**	**Cat. N.**	**Name**
YB500032	TGS TA – Toxo IgG	IS-ID5001	IDS Toxo IgG
YB500033	TGS TA – Toxo IgM	IS-ID5002	IDS Toxo IgM
YB500034	TGS TA – Toxo IgG Avidity	IS-ID5101	IDS Toxo IgG Avidity
YB500040	TGS TA – Toxo Control Set	IS-ID5030	IDS Toxo Control Set
YB500041	TGS TA – Toxo Avidity Control Set	IS-ID5130	IDS Toxo Avidity Control Set

after ensuring its conformity to Directive 98/79/EC, through the procedure relevant to the EC Declaration of Conformity according to Annex IV to the Directive - Full Quality Assurance System Certificate N° 9861 rev. 10, issued by the Notified Body LNE/G-Med (0459), 1 rue Gaston Boissier - 75724 Paris Cedex 15 – France, on December 7th, 2018.

HEREBY DECLARES

that the above mentioned device fulfils all the provisions listed in the Medical Device Directive 98/79/EC as amended.

Therefore, Technogenetics assures, under its own responsibility, that:

- *"CLIA Kits for infectious diseases (Type C): Toxoplasmosis"* is classified as in vitro diagnostic medical devices, which is included in the List B of Annex II of 98/79/EC IVDD;

TECHNOGENETICS S.p.A.

SEDE OPERATIVA:
Via della Filanda 24-26 - 26900 - Lodi

Tel - 0039 0371 1921800
Fax - 0039 0371 610029

PEC: info@cert.technogenetics.it
www.technogenetics.it

SEDE LEGALE:
Via Privata Cesare Battisti, 1 - 20122 - Milano

Capitale sociale € 1.300.000 int. vers.

C.C.I.A.A. Milano 1232682
Iscr. Trib. Milano 283273/7246/23
Reg. Imprese C.F. 06614040159
P.I. 09279340153

- the above mentioned in vitro diagnostic medical device satisfy the essential requirements in the Annex I of the national legislative regulations referring to 98/79/EC In Vitro Diagnostic Medical Device Directive and subsequent changes;
- has followed the Conformity assessment procedure as per Annex IV to 98/79/EC IVDD;
- the above mentioned in vitro diagnostic medical devices is not intended for performance evaluation;
- the above mentioned in vitro diagnostic medical devices is not intended for self-diagnosis;
- the above mentioned in vitro diagnostic medical devices does not include sterile components;
- the Manufacturer commits to filing and to making available to the competent Authorities the technical documentation for a period of at least 5 years from the date of production of the last batch.

Lodi, 04/01/2022

TECHNOGENETICS S.p.A.

SEDE OPERATIVA:
Via della Filanda 24-26 - 26900 - Lodi

Tel - 0039 0371 1921800
Fax - 0039 0371 610029

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SEDE LEGALE:
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Capitale sociale € 1.300.000 int. vers.

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Iscr. Trib. Milano 283273/7246/23
Reg. Imprese C.F. 06614040159
P.I. 09279340153

immunodiagnosticsystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, BS EN ISO 23640:2015, BS EN ISO 18113-2:2011, BS EN ISO 15223-1:2016
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	IDS-iSYS Diluent A (Cat. No. IS-10DA)
GMDN Code:	58237
CE Marking:	26th June 2013
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Ver. 06

immunodiagnosticsystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, BS EN ISO 23640:2015, BS EN ISO 18113-2:2011, BS EN ISO 15223-1:2016
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	IDS-iSYS Diluent B (Cat. No. IS-10DB)
GMDN Code:	58237
CE Marking:	26th June 2013
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Ver. 06

immunodiagnosticsystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, BS EN ISO 23640:2015, BS EN ISO 18113-2:2011, BS EN ISO 15223-1:2016
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	IDS-iSYS Diluent C (Cat. No. IS-10DC)
GMDN Code:	58237
CE Marking:	08th August 2017
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Declaration of Conformity

Standards complied with:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 18113-3:2011 EN ISO 15223-1:2016 IEC 61010-2-101: 2018 IEC 61326-2-6: 2012 IEC 62304: 2006/amd1 :2015 IEC 62366: 2014 EN 50581: 2012
Manufacturer:	ImmunoDiagnostic Systems France, 42 rue Stéphane Mazeau, 21320 Pouilly en Auxois, FRANCE
Device:	IDS-iSYS Multi-Discipline Automated System (Cat No. IS-310400)
GMDN Code:	56725
CE Marking:	11th December 2008 for IVD and 22th July 2016 for RoHs
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

I, the undersigned, the duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant parts of the above legislation transposing the European In Vitro Diagnostic Medical Devices Directive 98/79/EC, the European Low Voltage Directive 2014/35/UE and the European Restriction of Hazardous substances Directive 2011/65/UE.

Position: Operations Director

24 June 2019
Date

Ver.1

IDS Ltd.
Immunodiagnostic Systems Limited,
10 Didcot Way, Boldon Business Park,
Boldon, Tyne & Wear, NE35 9PD UK
T: +44 (0) 191 519 0660 E: info.uk@idsplc.com
F: +44 (0) 191 519 0760 W: www.idsplc.com

immunodiagnosticsystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, BS EN ISO 23640:2015, BS EN ISO 18113-2:2011, BS EN ISO 15223-1:2016
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	IDS CCP (Cat No. IS-AI1201)
GMDN Code:	61080
CE Marking:	16th April 2018
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

immunodiagnosticsystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, BS EN ISO 23640:2015, BS EN ISO 18113-2:2011, BS EN ISO 15223-1:2016
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	IDS MPO (Cat No. IS-AI1701)
GMDN Code:	59008
CE Marking:	16th April 2018
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Ver.04

immunodiagnosticsystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, BS EN ISO 23640:2015, BS EN ISO 18113-2:2011, BS EN ISO 15223-1:2016
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	IDS PR3II (Cat No. IS-AI1702II)
GMDN Code:	59066
CE Marking:	30th July 2020
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Ver.02

immunodiagnosticsystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, BS EN ISO 23640:2015, BS EN ISO 18113-2:2011, BS EN ISO 15223-1:2016
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	IDS GBM (Cat No. IS-AI1703)
GMDN Code:	59065
CE Marking:	16th April 2018
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

immunodiagnosticsystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, BS EN ISO 23640:2015, BS EN ISO 18113-2:2011, BS EN ISO 15223-1:2016
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	IDS ANCA/GBM Control Set (Cat No. IS-AI1730)
GMDN Code:	41386 – PR3 42250 – MPO 54955 - GBM
CE Marking:	16th April 2018
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Ver.04

immunodiagnosticsystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971: *2019*, BS EN ISO 23640: *2015*, BS EN ISO 18113-2: *2011*, BS EN ISO 15223-1: *2016*.
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest solvay 101 4000, Liege Belgium.
Device:	IDS Calprotectin (Cat No. IS-AI26000)
GMDN Code:	62675
CE Marking:	28th February 2022
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

This declaration of conformity is issued under the sole responsibility of the manufacturer. We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 28th February 2022 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 28th February 2022 Signed on behalf of Immunodiagnostic Systems Limited:

Ver.01

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971: *2019*, BS EN ISO 23640: *2015*, BS EN ISO 18113-2: *2011*, BS EN ISO 15223-1: *2016*.
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest solvay 101 4000, Liege Belgium.
Device:	IDS Calprotectin Calibrator Set (Cat No. IS-AI26020)
GMDN Code:	53625
CE Marking:	28th February 2022
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

This declaration of conformity is issued under the sole responsibility of the manufacturer. We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 28th February 2022 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 28th February 2022 Signed on behalf of Immunodiagnostic Systems Limited:

Ver.01

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971: *2019*, BS EN ISO 23640: *2015*, BS EN ISO 18113-2: *2011*, BS EN ISO 15223-1: *2016*.
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest solvay 101 4000, Liege *Belgium*.
Device:	IDS Calprotectin Control Set (Cat No. IS-AI26030)
GMDN Code:	53626
CE Marking:	28th February 2022
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

This declaration of conformity is issued under the sole responsibility of the manufacturer. We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 28th February 2022 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 28th February 2022 Signed on behalf of Immunodiagnostic Systems Limited:

Ver.01

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971: *2019*, BS EN ISO 23640: *2015*, BS EN ISO 18113-2: *2011*, BS EN ISO 15223-1: *2016*.
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest solvay 101 4000, Liege *Belgium*.
Device:	IDS Calprotectin Extraction Device (Cat No. IS-AI26040)
GMDN Code:	65197
CE Marking:	28th February 2022
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

This declaration of conformity is issued under the sole responsibility of the manufacturer. We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 28th February 2022 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 28th February 2022 Signed on behalf of Immunodiagnostic Systems Limited:

Ver.01

immunodiagnostiosystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, BS EN ISO 15223-1:2016 IEC 62366-1:2015
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	IDS-iSYS Cuvettes (Cat No. IS-CC100)
GMDN Code:	61032
CE Marking:	22th November 2007
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Ver 06

Declaration of Conformity

According to Annex III, Directive 98/79/EC

Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, EN ISO 13641:2002, EN 13612:2002, EN ISO 23640:2015, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN ISO 15223-1:2016, EN IEC 62366-1:2015 +A1:2020.
Manufacturer:	Immunodiagnostic Systems SA, Rue Ernest Solvay 101, 4000 LIEGE BELGIUM
Device:	IDS-iSYS System Liquid (Syst. I) REF IS-CS100
GMDN Code:	59058
CE Marking:	04th October 2011
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, the duly authorised representatives of Immunodiagnostic Systems SA, declare that the device specified above complies with the relevant parts of the above legislation transposing the European In Vitro Diagnostic Medical Devices Directive 98/79/EC.

Date: 14th January 2022 Signed on behalf of Immunodiagnostic Systems SA:

Immunodiagnostic Systems
SA
Rue Ernest Solvay 101, 4000 LIEGE
BELGIUM
Tel. (32)4/252.26.36 - Fax (32)4/252.51.96

Ver.07

Declaration of Conformity

According to Annex III, Directive 98/79/EC

Standards complied with:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 13641:2002, EN 13612:2002, EN ISO 23640:2015, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN ISO 15223-1:2016, EN IEC 62366-1:2015
Manufacturer:	Immunodiagnostic Systems SA Rue Ernest Solvay 101, 4000 LIEGE BELGIUM
Device:	IDS-iSYS Trigger Set REF IS-CT100
GMDN code :	56725
CE Marking:	07th February 2019
Classification:	General IVD pursuant to the Directive 98/79/EC

We, the undersigned, the duly authorized representative of Immunodiagnostic Systems SA, declare that the device specified above complies with the relevant parts of the above legislation transposing the European In Vitro Diagnostic Medical Devices Directive 98/79/EC.

Date: 30th April 2019

Signed on behaf of Immunodiagnostic Systems SA

Ver.08

Declaration of Conformity

According to Annex III, Directive 98/79/EC

Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, EN ISO 13641:2002, EN 13612:2002, EN ISO 23640:2015, EN ISO 18113-2:2011, EN ISO 18113-3:2011, EN ISO 15223-1:2016, EN IEC 62366-1:2015 +A1:2020.
Manufacturer:	Immunodiagnostic Systems SA, Rue Ernest Solvay 101, 4000 LIEGE BELGIUM
Device:	IDS-iSYS Wash Solution (Wash S) REF IS-CW100
GMDN Code:	59058
CE Marking:	04th October 2011
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, the duly authorised representatives of Immunodiagnostic Systems SA, declare that the device specified above complies with the relevant parts of the above legislation transposing the European In Vitro Diagnostic Medical Devices Directive 98/79/EC.

Date: 14th January 2022 Signed on behalf of Immunodiagnostic Systems SA:

Immunodiagnostic Systems
SA
Rue Ernest Solvay 101, 4000 LIEGE
BELGIUM
Tel. (32)4/252.26.36 - Fax (32)4/252.51.96

Ver.08

TECHNO GENETICS
a BOUTY company

DECLARATION OF CONFORMITY

The undersigned Technogenetics S.r.l., with legal address at 4 Via Vanvitelli, 20129 Milano, and operation sites site at 26 Via Della Filanda, 26900 Lodi (LO), Italy, C.F. 06614040159, hereby declares under its own responsibility that, the in vitro diagnostic medical device:

➢ **DECONTAMINANT SOLUTIONS FOR ANALYZER DISPENSING TIP:**

D-SORB SOLUTION	
CODE	**BRANDNAME**
IS-DS100	D-SORB

fulfils all the provisions listed in the Medical Device Directive 98/79/EC as amended.

Therefore, Technogenetics assures, under its own responsibility, that:

- "Decontaminant solutions for analyzer dispensing tip" are classified as in vitro diagnostic medical devices, which are not included in Annex II of 98/79/EC IVDD, and subsequent changes, and are not IVDs for performance evaluation;
- the above mentioned in vitro diagnostic medical devices satisfy the essential requirements in the Annex I of the national legislative regulations referring to 98/79/EC In Vitro Diagnostic Medical Device Directive and subsequent changes;
- has followed the Conformity assessment procedure as per Annex III, except paragraph 6, because "Decontaminant solutions for analyzer dispensing tip" are not IVDs for self-testing (according to 98/79/EC IVDD and subsequent changes);
- prepare and keep available to the competent Authorities the technical documentation as specified in Annex III to the aforementioned directive for a period of at least five years from the date of production of the last batch.

Lodi, 31.07.2014

TECHNOGENETICS S.r.l. - unico socio BOUTY S.p.A.

SEDI OPERATIVE:
- S.S. N° 11, Padana Superiore Km 160
  20060 CASSINA DE' PECCHI (MI)
- Via della Filanda 30
  26900 LODI
- Via della Filanda 26
  26900 LODI

Tel. 02 26 289.1 (sel. Passante)
Fax 0371 610029
e-mail: bouty@bouty.it
www.technogenetics.it

SEDE LEGALE:
Via Vanvitelli, 4 - 20129 (MI)
Capitale sociale € 1.300.000
C.C.I.A.A. Milano 1232682
Iscr. Trib. Milano 283273/7246/23
Reg. Imprese C.F. 06614040159
P.I. 09279340158
Direzione e coordinamento BOUTY S.p.A.

Immunodiagnosticsystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2016, BS EN ISO 14971:2019, BS EN ISO 23640:2015, BS EN ISO 18113-2:2011, BS EN ISO 15223-1:2016
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	IDS Immunocleaner (Cat No. IS-IM100)
GMDN Code:	59058
CE Marking:	10th August 2018
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Ver 03

immunodiagnosticsystems

Declaration of Conformity

UK Statutory Instrument:	Statutory Instrument 2002 No. 618, The Medical Devices Regulations 2002 (as amended).
Standards complied with:	BS EN ISO 13485:2012, BS EN ISO 14971:2019, BS EN ISO 13612:2002, BS EN ISO 18113-3:2011, BS EN ISO 15223-1:2016, IEC 62304:2006, IEC 62366:2014.
Manufacturer:	Immunodiagnostic Systems Limited, 10 Didcot Way, Boldon Business Park, Boldon, Tyne & Wear, NE35 9PD, UK.
European Authorised Representative:	Immunodiagnostic Systems SA Rue Ernest Solvay 101 4000, Liege Belgium.
Device:	IDS-iSYS SDSpeed Calc (Cat No. IS-SDSCALC)
EDMA Code:	20 02 10 01
GMDN Code:	56725
CE Marking:	27th February 2015
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

We, the undersigned, are duly authorised representatives of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant sections of Annex III of the European In Vitro Diagnostic Medical Devices Directive 98/79/EC applicable to the above classification.

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Date: 05 November 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Declaration of Conformity

Directives complied with:	The Low Voltage Directive 2014/35/EU Electro-magnetic Compatibility Directive 2014/30/UE RoHs2 Directive 2011/65/UE Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/UE Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation 1907/2006
Standards complied with:	IEC 61010-2-51:2018, IEC 61010-1:2010 / Amd1:2016, IEC 61326-1:2012, ISO 13485:2016, EN 50419:2006 BS EN IEC 63000:2018,
Manufacturer:	Immunodiagnostic Systems France SAS, 42 rue Stephane Mazeau, 21320, Pouilly-en-Auxois, France.
Device:	IDS-iSYS XPrep (Cat No. IS-XP01)
GMDN Code:	56725
CE Marking:	23rd May 2016

I, the undersigned, the duly authorised representative of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant parts of the above Standards and Directives.

Date: 16th January 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Ver.02

immunodiagnosticsystems

Declaration of Conformity

Standards complied with:	EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 18113-3:2011 EN ISO 15223-1:2016 IEC 61010-1:2010 / Amd1:2016 IEC 61010-2-101:2018 IEC 61326-2-6:2012 IEC 62304:2006 / Amd1:2015 IEC 62366:2014 BS EN IEC 63000:2018 EN 50419:2006
Manufacturer:	ImmunoDiagnostic Systems France, 42 rue Stéphane Mazeau, 21320 Pouilly en Auxois, FRANCE
Device:	TGS TA (Cat. No. TGS00001)
GMDN Code:	56725
CE Marking:	12th September 2012 for IVD and 22nd July 2016 for RoHs
Classification:	General IVD pursuant to Article 9, Directive 98/79/EC

I, the undersigned, the duly authorised representative of Immunodiagnostic Systems Limited, declare that the device specified above complies with the relevant parts of the above legislation transposing the European In Vitro Diagnostic Medical Devices Directive 98/79/EC, the European Low Voltage Directive 2014/35/UE, European Restriction of Hazardous Substances Directive 2011/65/UE, Waste Electrical and Electronic Weuipments (WEEE) Directive 2012/49/UE and the Registration, Evaluation, Authorisation and Registration of Chemicals (REACH) Regulation 1907/2006.

Date: 16th January 2020 Signed on behalf of Immunodiagnostic Systems Limited:

Ver. 02

DECLARATION OF CONFORMITY

The undersigned Technogenetics S.p.A., with legal address at 1, via Privata Cesare Battisti, 20122 Milano, and operation sites site at 24-26 Via Della Filanda, 26900 Lodi (LO), Italy, C.F. 06614040159, hereby declares under its own responsibility that, the in vitro diagnostic medical devices:

Cat. N.	Name
IS-ID6501S	IDS SARS-CoV-2 S1-RBD IgG
IS-ID6530S	IDS SARS-CoV-2 S1-RBD Control Set

fulfil all the provisions listed in the Medical Device Directive 98/79/EC as amended.
Therefore, Technogenetics assures, under its own responsibility, that:

- "IDS SARS-CoV-2 S1-RBD IgG" and "IDS SARS-CoV-2 S1-RBD Control Set" are classified as in vitro diagnostic medical devices, which are not included in Annex II of 98/79/EC IVDD, and subsequent changes, and are not IVDs for performance evaluation;
- the above mentioned in vitro diagnostic medical devices satisfy the essential requirements in the Annex I of the national legislative regulations referring to 98/79/EC In Vitro Diagnostic Medical Device Directive and subsequent changes;
- have followed the Conformity assessment procedure as per Annex III, except paragraph 6, because "IDS SARS-CoV-2 S1-RBD IgG" and "IDS SARS-CoV-2 S1-RBD Control Set" are not IVDs for self-testing (according to 98/79/EC IVDD and subsequent changes);
- prepare and keep available to the competent Authorities the technical documentation as specified in Annex III to the aforementioned directive for a period of at least five years from the date of production of the last batch.

Lodi, 22-02-2022

TECHNOGENETICS S.p.A.

SEDE OPERATIVA:
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