Către Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE
pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. 60 din 18.12.2023

Solicitantul Sanmedico SRL cod fiscal 1003602008154, cu adresa juridică: mun. Chișinău str. Corobceanu 7A ap.9, cu sediul în mun. Chișinău, str. Petricani 88/1, oficiul 10, tel./fax: 022-62-30-32, e-mail sanmedico.office@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

071011	Set ELISA	ADALTIS	HBSAG 96 TESTS
071012	Set ELISA	ADALTIS	HBSAG 192 TESTS
071067	Set ELISA	ADALTIS	HCV AB 96 TESTS
071064	Set ELISA	ADALTIS	HCV AB 192 TESTS

Se anexează următoarele acte:

Declarația de conformitate CE
Autorizația de la producător
Declarația pe propria răspundere

Data 18.12.2023 Semnătura _____

Tabelul de recepționare a notificării
(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	Digitally signed by Monastîrschii Viorica Date: 2023.12.14 15:40:58 EET Reason: MoldSign Signature Location: Moldova
Semnătura persoanei responsabile	

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SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

bqs. s.r.o.
Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

EC Certificate IVDD 22 012 0147

EC Design-Examination Certificate

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

Certificate holder: **Adaltis S.r.l.**
Via Durini 27, 20122 Milano, Italy

Other Facility(ies): Via Luigi Einaudi 7, 00012 Guidonia Montecelio (RM), Italy

The certificate was issued with respect to the following scope:

ElAgen HBsAg Kit

This certificate is effective from 25 May 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 25 May 2022.

Certification has been authorized by

Digitally signed by Radovan Máčaj

Radovan Macaj
Head of Notified body

bqs.
Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed an examination of the design dossier in accordance with Annex IV section 4 of the directive and found that the design of the device conforms to the requirements laid down by Annex IV. For the placing on the market of List A devices an EC full quality assurance to Annex IV is required. Please see also notes overleaf if any.

SNAS
Reg. No. 575/P-051

Notified body 2854 | SKTC-180

bqs. s.r.o.
Studentska 12, 911 01
Trencin | Slovakia
www.bqsgroup.eu

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Additional information on certification

Related to certificate number:

IVDD 22 012 0147

Description of product(s) within the certification scope:

EIAgen HBsAg Kit is an enzyme-linked immunosorbent assay (ELISA) for qualitative detection of HBsAg in human serum or plasma. It is intended for screening of blood donors and for diagnosing of patients related to infection with hepatitis B virus.

Types/Categories/Models:	071011 (96 tests) 071012 (192 tests) 071015 (480 tests)
Classification:	List A
Validity conditions:	-

This certificate is effective from 25 May 2022 until 26 May 2025 and remains valid subject to execution of regular examinations and continuous compliance.
Initial version of the certificate was effective from 25 May 2022.

bqs.
Certified In Vitro diagnostic medical device

bqs issued the certificate on the basis of performed examination in accordance with Council Directive 98/79/EC, Slovak government decree No. 569/2001 Coll. of Laws and EN ISO/IEC 17065:2012. Notified Body has performed an examination of the design dossier in accordance with Annex IV section 4 of the directive and found that the design of the device conforms to the requirements laid down by Annex IV. For the placing on the market of List A devices an EC full quality assurance to Annex IV is required. Please see also notes overleaf if any.

ATTESTATION/ *CERTIFICATE* **N° 20102 rev. 7**

Délivrée à Paris le 05 avril 2022

Issued in Paris on April 5th, 2022

ATTESTATION CE / *EC CERTIFICATE*

Examen CE de type */ EC Type Examination*

ANNEXE V Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro

ANNEX V DIRECTIVE 98/79/EC concerning in vitro diagnostic medical devices

Fabricant */ Manufacturer*

ADALTIS S.R.L.

Via Durini 27

20122 MILANO ITALY

Catégorie du(des) dispositif(s) */ Device(s) category*

Dispositif médical de diagnostic in vitro destiné à la détermination des marqueurs d'infections humaines relatives à l'Hépatite C basé sur une technique immunoenzymatique.

In vitro dignostic medical device intended for the determination of markers of human infections related to Hepatitis C on enzyme immunoassay test method.

Identification du(des) dispositif(s) */ Identification of device(s)*

ElAgen HCV Ab (v.4) Kit

ElAgen HCV Ab (v.4) Kit

Voir document complémentaire GMED / See GMED additional document

n° 38929

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P602876 - P604613, un échantillon représentatif de la production est conforme aux exigences de l'annexe I de la directive 98/79/CE.

GMED certifies that, on the basis of the results contained in the file referenced P602876 - P604613, a representative sample of the production complies with the requirements of the directive 98/79/EC, annex 1.

Début de validité */ Effective date :* **April 5th, 2022 (included)**

Valable jusqu'au */ Expiry date :* **May 26th, 2025 (included)**

DocuSigned by:
Béatrice LYS
EF33BDA9BAA04A3...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President
Béatrice LYS
Technical Director

GMED_c5-F-new2021-V0-09-

GMED - 20102 rev. 7
Modifie le certificat 20102-6

Délivré à Paris le 05/04/2022
Issued in Paris on 04/05/2022

Ce document complémentaire GMED n° 38929 rev. 0 atteste de la validité du certificat CE n° 20102 rev. 7 au regard des informations listées ci-dessous.

This GMED additional document n° 38929 rev. 0 attests to the validity of CE certificate n° 20102 rev. 7 with regard to the information listed below.

Fabricant / *Manufacturer:*

ADALTIS S.R.L.
Via Durini 27
20122 MILANO ITALY

Identification des dispositifs / *Identification of devices*

Désignation du dispositif - Accessoires marqués CE/ *Device designation - CE marked accessories*	**Référence commerciale ou code article/** *Commercial reference or article code*	**Code GMDN** GMDN code
ElAgen HCV Ab (v.4) Kit	071064 / 071067 / 071068	48365

GMED	0459

GMED - 38929 rev. 0

DocuSigned by:
Béatrice LYS
On behalf of the President
Béatrice LYS
Technical Director

ATTESTATION/ *CERTIFICATE* **N° 20109 rev. 6**

Délivrée à Paris le 13 mai 2022

Issued in Paris on May 13th, 2022

ATTESTATION CE / *EC CERTIFICATE*

Approbation du Système d'assurance Qualité de la Production / *Approval of Production Quality Assurance System*

ANNEXE VII point 3 Directive 98/79/CE relative aux dispositifs médicaux de diagnostic in vitro

ANNEX VII section 3 DIRECTIVE 98/79/EC concerning in vitro diagnostic medical devices

Pour les dispositifs des listes A et B IVD, un certificat CE de type est requis

For list A and list B IVD devices, a EC type certificate is required

Fabricant / *Manufacturer*

ADALTIS S.R.L.

Via Durini 27

20122 MILANO ITALY

Catégorie du(des) dispositif(s) / *Device(s) category*

Dispositifs médicaux de diagnostic in vitro destinés à la détermination des marqueurs d'infections humaines relatives à l'Hépatite C basée sur des techniques immunoenzymatiques.

In vitro diagnostic medical devices intended for the determination of markers of human infections related to Hepatitis C based on enzyme immunoassay test methods.

Voir document complémentaire GMED / See GMED additional document

n° 38904

GMED atteste qu'à l'examen des résultats figurant dans le rapport référencé P604613, le système d'assurance qualité - pour la production et le contrôle final - des dispositifs médicaux énumérés ci-dessus est conforme aux exigences de l'annexe VII point 3 de la Directive 98/79/CE.

GMED certifies that, on the basis of the results contained in the file referenced P604613, the quality system - for manufacturing and final inspection - of medical devices listed here aboved complies with the requirements of the Directive 98/79/EC, annex VII section 3.

La validité du présent certificat est soumise à une vérification périodique ou imprévue
The validity of the certificate is subject to periodic or unexpected verification

Début de validité / *Effective date :* **May 13th, 2022 (included)**

Valable jusqu'au / *Expiry date :* **March 25th, 2025 (included)**

DocuSigned by:
Beatrice Lys
EF33BDA9BAA04A3...

GMED SAS GMED SAS GMED GROUPE LNE

On behalf of the President

Béatrice LYS

Technical Director

GMED_c7-F-new2021-V0-09-

GMED - 20109 rev. 6
Renouvelle le certificat 20109-5

Délivré à Paris le 13/05//2022
Issued in Paris on 05/13/2022

Ce document complémentaire GMED n° 38904 rev. 0 atteste de la validité du certificat CE n° 20109 rev. 6 au regard des informations listées ci-dessous.

This GMED additional document n° 38904 rev. 0 attests to the validity of CE certificate n° 20109 rev. 6 with regard to the information listed below.

Fabricant / *Manufacturer:*

ADALTIS S.R.L.
Via Durini 27
20122 MILANO ITALY

Identification des dispositifs / *Identification of devices*

Désignation du dispositif - Accessoires marqués CE/ *Device designation - CE marked accessories*	**Référence commerciale ou code article/** *Commercial reference or article code*	**Classe du DM/** *DM Class*
ElAgen HCV Ab (v.4) Kit	**071064 / 071067 / 071068**	**Annex II A**
Diagnostic Kit for Antibody to Hepatitis C Virus (ELISA)	**071064-C / 071067-C**	

Sites couverts et Activités / *Locations and Activities*

- **ADALTIS S.R.L. –** Via Durini 27, 20122 MILANO, ITALY
  Siège social, responsable de la mise sur le marché/ *Headquarter, legal manufacturer*
- **ADALTIS S.R.L. –** Via Luigi Einaudi, 00012 Guidonia Montecelio ROMA, ITALY
  Activités de fabrication et de contrôle final / *Manufacturing and final control activities*

GMED	0459

GMED - 38904 rev. 0

DocuSigned by:
Beatrice Lys
DF336DA8BAA0479...

On behalf of the President
Béatrice LYS
Technical Director

DICHIARAZIONE DI CONFORMITÀ "CE" PER DISPOSITIVI MEDICI DIAGNOSTICI IN VITRO

EC Declaration of Conformity for IN VITRO DIAGNOSTIC MEDICAL DEVICES

La sottoscritta, fabbricante,
We, the undersigned manufacturer

Adaltis S.r.l.
Con Sede Legale in
Whit Registered Office in

Via Durini, 27
20122 Milano - Italy

Adaltis S.r.l.
Con Sede Produttiva in
With Manufacturing Site in

Via Luigi Einaudi, 7
00012 Guidonia Montecelio (RM) - Italy

Dichiara sotto la propria responsabilità che il prodotto descritto di seguito:
Herewith declare under our sole responsibility that the product described here below:

EIAgen HBsAg Kit

Codici/Codes 071011 / 071012 / 071015 - Nr. 96 / 192 / 480 tests

E' CLASSIFICATO COME DISPOSITIVO DIAGNOSTICO IN VITRO APPARTENENTE ALL'"ALLEGATO II Lista A"; VALUTAZIONE DELLA CONFORMITA' SECONDO:
ALLEGATO IV eccetto sezioni 4 & 6 certificato N. IVDD 22 012 0146 Scadenza 2025-05-26;
ALLEGATO IV paragrafo 4 certificato N. IVDD 22 012 0147 Scadenza 2025-05-26;
Ente Notificato: bqs. s.r.o. 2854

is classified as a IVD listed in Annex II List A; conformity assessment route:
ANNEX IV excluding sections 4 & 6 certificate N. IVDD 22 012 0146 Exp. Date 2025-05-26
ANNEX IV paragraph 4 certificate N. IVDD 22 012 0147 Exp. Date 2025-05-26;
Notified Body: bqs. s.r.o. 2854

Ed è in conformità con i requisiti della
And it is in compliance with the requirements of the

DIRETTIVA 98/79/CE IVDD del Parlamento europeo e del Consiglio, del 27 ottobre 1998, relativa ai dispositivi medico-diagnostici in vitro, pubblicata nella Gazzetta Ufficiale il 7 dicembre 1998.
EC COUNCIL DIRECTIVE IVDD 98/79/CE of the European Parliament and of the Council of 27th October 1998 of In Vitro Diagnostic Medical Device, published in the Official Journal on 7th December 1998.

Inoltre, sono applicate le seguenti Norme Armonizzate:
In addition, the following Harmonized Standards are applied:
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 13612:2002, EN 62366-1:2015, EN ISO 23640:2015 and CTS.

The product is in compliance with Common Technical Specifications as they are defined within Commission Decision (2009/886/EC) of 27 November 2009 amending Decision 2002/364/EC on Common Technical Specifications for in vitro diagnostic medical devices

La documentazione tecnica a dimostrazione della conformità è conservata dal produttore e può essere resa disponibile da Adaltis S.r.l.
Technical documentation demonstrating compliance is kept by the manufacturer and can be made available by Adaltis S.r.l.

Prima Emissione/*First Emission*: ___*26 May 2022*___ /___*26 Maggio 2022*__

_____
RESPONSABILE ASSICURAZIONE QUALITA' & AFFARI REGOLATORI / Quality Assurance & Regulatory Affairs Manager
(Roberto Steinhaus)

_____
DIRETTORE GENERALE / General Manager
(Marco Spadaccioli)

Place Guidonia Montecelio Rome - Italy

DICHIARAZIONE DI CONFORMITÀ "CE" PER DISPOSITIVI MEDICI DIAGNOSTICI IN VITRO

EC Declaration of Conformity for IN VITRO DIAGNOSTIC MEDICAL DEVICES

La sottoscritta, fabbricante,
We, the undersigned manufacturer

Adaltis S.r.l.

Con Sede Legale in
Whit Registered Office in

Via Durini, 27
20122 Milano - Italy

Dichiara sotto la propria responsabilità che il prodotto descritto di seguito:
Herewith declare under our sole responsibility that the product described here below:

EIAgen HCV Ab (v.4) Kit

Codici/Codes 071067 / 071064 / 071068 - Nr. 96 / 192 / 480 tests

E' CLASSIFICATO COME DISPOSITIVO DIAGNOSTICO IN VITRO APPARTENENTE ALL'"ALLEGATO II Lista A"; VALUTAZIONE DELLA CONFORMITA' SECONDO: ALLEGATO V certificato N. 20102 Rev.7 e documento aggiuntivo N. 38929 Rev.0. ALLEGATO VII certificato N. 20109 Rev.6 e documento aggiuntivo N. 38904 Rev.0. Ente Notificato: GMED 0459

is classified as a IVD listed in Annex II List A; conformity assessment route:
ANNEX V certificate N. 20102 Rev.7 and addition document N. 38929 Rev.0.
ANNEX VII certificate N. 20109 Rev.6 and addition document N. 38904 Rev.0.
Notified Body: GMED 0459

Ed è in conformità con i requisiti della
And it is in compliance with the requirements of the

DIRETTIVA 98/79/CE IVDD del Parlamento europeo e del Consiglio, del 27 ottobre 1998, relativa ai dispositivi medico-diagnostici in vitro, pubblicata nella Gazzetta Ufficiale il 7 dicembre 1998.
EC COUNCIL DIRECTIVE IVDD 98/79/CE of the European Parliament and of the Council of 27th October 1998 of In Vitro Diagnostic Medical Device, published in the Official Journal on 7th December 1998.

Inoltre, sono applicate le seguenti Norme Armonizzate:
In addition, the following Harmonized Standards are applied:
EN ISO 13485, EN ISO 14971, EN 13641, EN ISO 18113 - PART 1 & 2, EN ISO 15223-1, EN 13612, EN 62366, EN ISO 23640

Prima Emissione/*First Emission*: ___*22 Novembre 2010*__ / __ *22 November 2010*__

Emissione Corrente/*Current Emission: __14 Maggio 2022___ /___ 14 May 2022__*

RESPONSABILE ASSICURAZIONE QUALITA' & AFFARI REGOLATORI / Quality Assurance & Regulatory Affairs Manager
(Roberto Steinhaus)

DIRETTORE GENERALE / General Manager
(Marco Spadaccioli)

To: **Agenţia Medicamentului şi Dispozitivelor Medicale**
Chisinau str. Korolenko 2/1
MD-2028 Moldova

MANUFACTURER AUTHORISATION FORM

Italy, 27 November 2023

We, Adaltis S.r.l., certified ISO 9001 and ISO 13485, as the manufacturer of In Vitro Diagnostic Medical Devices (Instruments and Reagents), with legal site in Via Durini 27, 20122 Milano - Italy and production site in Via Luigi Einaudi 7, 00012 Guidonia Montecelio (RM) – Italy,

we hereby authorise company **SRL SANMEDICO** having a registered office at A. Corobceanu street 7A, apt. 9, Chişinău MD-2012, Moldova,

to register with entitled institutions in Moldova, to commercialise as our distributor, to proceed and sign and submit offers and sign contracts on their behalf, deliver the goods for the following of our products for the tender/ project '*CENTER FOR CENTRALIZED PUBLIC PROCUREMENT IN HEALTH, no. ocds-b3wdp1-MD-1699619738481, The centralized purchase of Reagents for the Immunological Laboratory according to the needs of public medical and sanitary institutions (IMSP) for the year 2024',* in Moldova:

- **ElAgen HCV Ab (v.4)** *item 071067 (96T/kit)*
- **ElAgen HCV Ab (v.4)** *item 071064 (192T/kit)*
- **ElAgen HBsAg** *item 071011 (96T/kit)*
- **ElAgen HBsAg** *item 071012 (192T/kit)*

This authorisation is issued 27 November 2023 and shall expire 12 (twelve) months later, for all purposes. This authorisation may be renewable on request only.

ADALTIS S.r.l.

Adaltis S.r.l.
Via Luigi Einaudi, 7
00012 Guidonia Montecelio - Roma
Cod. Fis. 06797400964
P. IVA 06797400964

Marc Eijkhout
Sales Director

Adaltis S.r.l.
Headquarter
Via Luigi Einaudi, 7
00012 Guidonia Montecelio (RM) - Italy
Tel. +39 0774 579.1
Fax +39 0774 353085
service@adaltis.net - info@adaltis.net

Legal site
Via Durini, 27
20122 Milano - Italy
Cap. Soc. € 11.000,00 - REA: MI1915413
C.F. 06797400964 - P.I. IT06797400964
order@adaltis.net - www.adaltis.net

Către Agenția Medicamentului și Dispozitive Medicale

DECLARATIE PE PROPRIE RĂSPUNDERE

Solicitant: Sanmedico SRL, cod fiscal 1003602008154, cu adresa juridică: mun. Chișinău, str. Corobceanu 7a, ap.9, cu sediul: str. Petricani 88/1, oficiul 10,

declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

071011	Set ELISA	ADALTIS	HBSAG 96 TESTS
071012	Set ELISA	ADALTIS	HBSAG 192 TESTS
071067	Set ELISA	ADALTIS	HCV AB 96 TESTS
071064	Set ELISA	ADALTIS	HCV AB 192 TESTS

Sunt autentice și corespund realității.

Vitalie Goreacii, administrator *Semnătura* _____

Data 18.12.2023

Nr.	Numărul de catalog (referință)*	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	071011	Set ELISA	ADALTIS	HBSAG 96 TESTS	
2	071012	Set ELISA	ADALTIS	HBSAG 192 TESTS	
3	071067	Set ELISA	ADALTIS	HCV AB 96 TESTS	
4	071064	Set ELISA	ADALTIS	HCV AB 192 TESTS	