

**Către Agenția Medicamentului
și Dispozitivelor Medicale**

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale nr. **181** din **26.06.2023**

“Health Medical Solutions” SRL, cu sediul Republica Moldova, MD-2019, mun. Chișinău, str. Grenoble 128, of. 011, E-mail: info@hms.md, srl.hms.moldova@gmail.com, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii și tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a dispozitivelor **clasa de risc I**:

1. Frigider pentru reactivi, denumire comercială - **Refrigerator**, model – **DS-PSM40BG**, producător- **DESMON S.p.A.**, țara de origine - **Italia**;

Se anexează următoarele acte:

1. Împuternicirea de a reprezenta **DESMON S.p.A., Italia** din 12/06/2023;
2. Declarația de conformitate CE;
3. Certificat ISO 13485:2016 No. 255772-2018-AQ-ITA-ACCREDIA, valabil 06 March 2021 – 05 March 2024;
4. Declarație pe proprie răspundere.

Data **26.06.2023**

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	
Semnătura persoanei responsabile	

DECLARAȚIE PE PROPRIE RĂSPUNDERE

“**Health Medical Solutions**” SRL, cu sediul Republica Moldova, MD-2019, mun. Chișinău, str. Grenoble 128, of. 011 E-mail: info@hms.md, srl.hms.moldova@gmail.com, declar pe proprie răspundere, cunoscând prevederile art. 352¹, Codul Penal al Republicii Moldova cu privire la falsul în declarații, că documentele și datele furnizate pentru notificarea dispozitivului medical:

1. Frigider pentru reactivi, denumire comercială - **Refrigerator**, model – **DS-PSM40BG**, producător- **DESMON S.p.A.**, țara de origine - **Italia**;

Sunt autentice și corespund realității.

Numele, prenumele și funcția

Lungu Ion, Administrator

+37379627404, +37369423432

Semnătura

Data 26.06.2023

Nusco, 12/06/2023

LETTER OF AUTHORIZATION

To Whom it May Concern,

We, **DESMON S.p.A.**, who are official manufacturer of biomedical refrigerators and freezers, having headquarters at Nusco (Italy) – Zona Industriale F3 Sup., assign - company **HEALTH MEDICAL SOLUTIONS S.R.L.**, based at Moldova Republic of, Chisinau, MD-2019, 128, Grenoble str., OF.011

- as authorized representative in the Republic of Moldova in correspondence with the conditions of ***Directive Regulation (EU) n. 2017/745.***
- We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the in territory of Republic of Moldova, and to perform Essential Duties required by Law No. 102 on 09.06.2017 regarding Medical Devices.

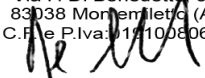
This Authorization letter is valid until 31/12/2023

Signature and stamp

For and on behalf of
Corrado De Santis
Director

DESMON S.p.A

DESMON S.p.A.
Via F. Di Benedetto, 35
83038 Montemiletto (Av)
C.F. e P.Iva: 01910080645



**DICHIARAZIONE DI CONFORMITA' / KONFORMITÄTSERKLÄRUNG/
DECLARATION OF CONFORMITY / DECLARATION DE CONFORMITE'**



Si attesta che la macchina qui di seguito specificata è del tutto conforme ai requisiti della Direttiva 2006/42/CE - 2014/68/UE (PED) - (CE) 1935/2004 (MOCA), 2012/19/UE (RAEE)-2011/65/UE (RoHS II)- 2011/65/UE-regolamento CE n. 1907/2006(REACH), e quanto indicato dalle norme armonizzate ed internazionali 2014/30/UE (EMC) e 2014/35/EU (Bassa tensione).

Wir bescheinigen, dass die Maschine, unten weiter spezifiziert, mit den Eigenschaften der Sondervorschrift 2006/42 EWG, 2014/68/UE (PED) - 2014/30/UE (EMC), 1935/2004 (MOCA), 2012/19 UE (RAEE)-2011/65/UE-2011/65/CE (RoHS II)- Bestimmung CE n.1907/2006(REACH)- UND 2014/35 EU - Übereinstimmt.

Wehereby certify that the machine spcified hereunder conforms in all respects to the requierements of the special directive 2006/42 EEC, 1935/2004 (MOCA), 2012/19/UE (RAEE)- 2014/68/UE (PED)-2011/65/UE- 2011/65/UE (RoHS II)-EC regulation n. 1907/2006(REACH) - and international Normative 2014/30/UE (EMC), and 2006/95 EEC.

On atteste que la macchione spècifièe ci-après est on tout conforme aux exigences de la directive 2006/42/CE,1935/2004 (MOCA), 2012/19/UE (RAEE)-2011/65/UE- 2011/65/CE (RoHS II)-reglement CE n.1907/2006(REACH),D, 2014/30/UE (EMC) et 2014/35 EU.

LAB GRADE REFRIGERATOR /FREEZER

DESMON S.p.A.

1. Categoria / Kategorie / Category / Catégorie

2. Costruttore / Hersteller / Manufacturer / Constructeur

00POP 000000

3.Tipo / Typbezeichnung / Type / Type

4. Numero serie / Seriennummer / Serial Number / Numéro de série

5. Anno di costruzione / Baujahr / Year of manufacture / Année de construction

Direttiva D.LGS 81/08 - CEI EN 61010 - CEI EN 61326 - EN 61000-3-2 - EN 61000-3-3 - CEI 66.5

6. Dati supplementari / Zusätzliche Daten / Additional information / Autres renseignements supplémentaires

Data / Datum / Date / Date :

2023.01.09

Firma / Unterschrift / Signature

**DESMON S.p.A.
Il Presidente
Dott. Corrado De Santis**

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
255772-2018-AQ-ITA-ACCREDIA

Initial certification date:
05 March 2018

Valid:
06 March 2021 – 05 March 2024

This is to certify that the management system of

DESMON S.p.A. - Sede Legale e Operativa

Zona Industriale F3 - 83051 Nusco (AV) - Italy

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016

This certificate is valid for the following scope:

Project Design, engineering, manufacturing, sale and after sales service of medical devices for plasma preservation and derivatives. such as blood banks refrigerator, plasma freezers and related accessories for the non-EU market

Place and date:
Vimercate (MB), 26 February 2021



SGQ N° 003 A	EMAS N° 009 P
SGA N° 003 D	PRD N° 003 B
SGE N° 007 M	PRS N° 094 C
SCR N° 004 F	SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento SGQ, SGA, PRD, PRS, ISP, GHG, LAB e LAT, di MLA IAF per gli schemi di accreditamento SGQ, SGA, SSI, FSM e PRD e di MRA ILAC per gli schemi di accreditamento LAB, MED, LAT e ISP

For the issuing office:
DNV GL - Business Assurance
Via Energy Park, 14, - 20871 Vimercate
(MB) - Italy

Zeno Beltrami
Management Representative

Certificate no.: 255772-2018-AQ-ITA-ACCREDIA
Place and date: Vimercate (MB), 26 February 2021

Appendix to Certificate

DESMON S.p.A. - Sede Legale e Operativa

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
DESMON S.p.A - Sede Operativa	Zona Industriale F3 superiore - 83051 Nusco (AV) - Italy	Project Design, engineering, manufacturing, sale and after sales service of medical devices for plasma preservation and derivatives such as blood banks refrigerator, plasma freezers and related accessories for the non-EU market
DESMON S.p.A. - Sede Legale e Operativa	Zona Industriale F3 - 83051 Nusco (AV) - Italy	Project Design, engineering, manufacturing, sale and after sales service of medical devices for plasma preservation and derivatives such as blood banks refrigerator, plasma freezers and related accessories for the non-EU market

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
CERT-04879-99-AQ-NPL-SINCERT

Initial certification date:
01 September 1999

Valid:
18 April 2022 – 17 April 2025

This is to certify that the management system of
DESMON S.p.A. - Sede Legale e Operativa
Zona Industriale F3 - 83051 Nusco (AV) - Italy
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:
ISO 9001:2015

This certificate is valid for the following scope:
Progettazione e produzione di frigoriferi, tavoli refrigeranti e celle frigorifere ad uso industriale (IAF: 18, 17)

Place and date:
Vimercate (MB), 03 February 2022



SGQ N° 003 A
SGA N° 003 D
SGE N° 007 M
SCR N° 004 F

EMAS N° 009 P
PRD N° 003 B
PRS N° 094 C
SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento
SGQ, SGA, PRD, PRS, ISP, GIG, LAB e LAT, di MLA IAF
per gli schemi di accreditamento SGQ, SGA, SSI, FSM
e PRD e di MRA ILAC per gli schemi di accreditamento
LAB, MED, LAT e ISP

For the issuing office:
DNV - Business Assurance
Via Energy Park, 14, - 20871 Vimercate (MB) - Italy



Claudia Baroncini
Management Representative

Appendix to Certificate

DESMON S.p.A. - Sede Legale e Operativa

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
DESMON S.p.A. - Sede Legale e Operativa	Zona Industriale F3 - 83051 Nusco (AV) - Italy	Reference to scope
DESMON S.p.A - Sede Operativa	Zona Industriale F3 superiore - 83051 Nusco (AV) - Italy	Reference to scope



MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:
129905-2013-AE-ITA-ACCREDIA

Initial certification date:
21 January 2013

Valid:
22 January 2022 – 21 January 2025

This is to certify that the management system of
DESMON S.p.A. - Sede Legale e Operativa
Zona Industriale F3 - 83051 Nusco (AV) - Italy
and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Environmental Management System standard:
ISO 14001:2015

This certificate is valid for the following scope:
Design, production and trade of industrial refrigerators and cold rooms by means of metal sheet cutting, body foaming, assembly and brazing of the refrigeration system (IAF 18, 17)

Place and date:
Vimercate (MB), 19 January 2022



SGQ N° 003 A
SGA N° 003 D
SGE N° 007 M
SCR N° 004 F

EMAS N° 009 P
PRD N° 003 B
PRS N° 094 C
SSI N° 002 G

Membro di MLA EA per gli schemi di accreditamento
SGQ, SGA, PRD, PRS, ISP, GIG, LAB e LAT, di MLA IAF
per gli schemi di accreditamento SGQ, SGA, SSI, FSM
e PRD e di MRA ILAC per gli schemi di accreditamento
LAB, MED, LAT e ISP

For the issuing office:
DNV - Business Assurance
Via Energy Park, 14, - 20871 Vimercate (MB) -
Italy



Claudia Baroncini
Management Representative

Appendix to Certificate

DESMON S.p.A. - Sede Legale e Operativa

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
DESMON S.p.A. - Sede Legale e Operativa	Zona Industriale F3 - 83051 Nusco (AV) - Italy	Reference to scope
DESMON S.p.A - Sede Operativa	Zona Industriale F3 superiore - 83051 Nusco (AV) - Italy	Reference to scope

