

Către Agenția Medicamentului și Dispozitivelor Medicale

NOTIFICARE

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

Solicitantul **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032, Chisinau, Republica Moldova**, tel./fax: **022 782 875**, e-mail: **irina.sandu@dita.md** 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
producătorului **HAROL S.R.L., Italia:**

- Mască de ventilare pentru terapia CPAP (conform Anexei 3)
- Mască respiratorie pentru VAP (conform Anexei 3)

Se anexează următoarele acte:

- Actul de reprezentanță între producător și reprezentantul autorizat în Republica Moldova;
- Declarația de conformitate CE;
- Certificat de conformitate CE;
- Declarația pe propria răspundere a solicitantului;
- Lista dispozitivelor medicale (format Excel).

Data 12.09.2023

Semnătura



Tabelul de receptionare 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	

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAȚIE PE PROPRIE RĂSPUNDERE

Solicitant: **Dita Estfarm SRL**, cu sediul **str-la Burebistra 23, MD-2032,**
Chisinau, Republica Moldova,

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 dispozitivelor medicale ale producătorului producătorului **HAROL S.R.L., Italia:**

- Mască de ventilare pentru terapia CPAP (conform Anexei 3)
- Mască respiratorie pentru VAP (conform Anexei 3)

Sunt autentice și corespund realității.

Numele, prenumele și funcția:

RA-Manager – Sandu Irina

Semnătura



Data **12.09.2023**

HAROL

We, Harol s.r.l.,

based in via G. Marcora 53, 20097 San Donato Milanese, (MI), **assign Dita Estfarm LLC**, based in No.23 Burebista street, Chisinau MD -2032, Republic of Moldova, as **authorized representative** in correspondence with the conditions of Regulation (EU) 93/42.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova.

Place: Milan Date: 01.08.2022

Signed:

HAROL S.r.l.
VIA MARCORA, 53
20097 SAN DONATO MILANESE (MI)
[Signature]



Production Quality Assurance System Approval Certificate

[Signature]

Expiry Date: 2024-05-08

HAROL

MEDICAL DEVICES FOR VENTILATION IN CPAP THERAPY AND ACCESSORIES – code list Annex 4 Edit 1 11/03/2019 – FT CPAP HAR

Emittente:AQ

Firma: *Collegato*

Approvato: DG

Firma: *Harol*

Medical Device for CPAP therapy in emergency

9200

9300/D

9293/D

9294/D

6000/10

6000



Accessories:

Reservoir bags:

6151/XX

151/XX

HAR151/XX

- XX field indicating the size in liters 0 to 30

Water valve:

6000/3

6000/R

6000/B

Masks and kit for ventilation in CPAP therapy and headstrap

9016/XS

9016/S

9016/M

9016/L

9016/XL



2019-05-09

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HAROL

9017

9021

9022

9023

9018

9018/1

9019

9019/1

1520-XXX-YYY

1560-XXX-YYY

9000/22

9000/30

9003

9005

9007

9010

9012

9015

9020



- XXX field indicating the different length of tubing from 30 to 300 cm
- YYY field indicating the different type of connectors, ventilation masks, PEEP valves and headstraps

CPAP10ZZZZZ

CPAP20ZZZZZ

CPAP30ZZZZZ

CPAP40ZZZZZ

CPAP50ZZZZZ

CPAP60ZZZZZ

CPAP70ZZZZZ



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CPAP80ZZZZZ

CPAP90ZZZZZ

- CPAP field indicating that the device is for CPAP therapy
- ZZZZZ field indicating the different type of connectors, ventilation masks, PEEP valves and headstraps

Helmet for CPAP and NIV therapy and accessories

002

006

CPAP 103ZZ/YYY

CPAP104ZZ/YYY

CPAP 105ZZ/YYY

CPAP 106ZZ/YYY

CPAP 107ZZ/YYY

CPAP 108ZZ/YYY

CPAP 109ZZ/YYY

NIV 103ZZ/YYY

NIV 104ZZ/YYY

NIV 105ZZ/YYY

NIV 106ZZ/YYY

NIV 107ZZ/YYY

NIV 108ZZ/YYY

NIV 109ZZ/YYY



- CPAP field indicating that the device is for CPAP therapy
- NIV field indicating that the device is for NIV therapy
- ZZ field indicating the different type of connectors, PEEP valves and tubing
- YYY field indicating the different type of size: NEO – PED – XS – S – M – L – XL – XXL – 3XL



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HAROL

DISPOSABLE MEDICAL DEVICES FOR VENTILATION AND ACCESSORIES – code list Annex 4 Edit 1 11/03/2019 – FT VENTIL HAR

Emittente:AQ

Firma: *Caligaris*

Approvato: DG

Firma: *Harmon*

Ventilation circuit

Model 400-XXX-YYY

Model 400/1-XXX-YYY

Model 401-XXX-YYY

Model 401/1-XXX-YYY

Model 402-X-YYY

Model 402/1-X-YYY

Model 403-XXX-YYY

Model 403/1-XXX-YYY

Model 1615-XXX-YYY

Model 1616-XXX-YYY

Model 1617-XXX-YYY

Model 1621-XXX-YYY

Model 1621/1-XXX-YYY

Model 1623-XXX-YYY

Model 1623/1-XXX-YYY

Model 405-XXX-YYY

Model 405/1-XXX-YYY

Model 406-XXX-YYY

Model 406/1-XXX-YYY

Model 1413-XXX-YYY

Size available for all the models

30-60-80-90-100-110-120-130-140-150-160-170-180-200-220-250-300

- HAR indicating that the device is supplied STERILE w/o is supplied not sterile
- XXX field indicating the different length of tubing from 30 to 300 cm



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- YYY field indicating the different type of connectors, ventilation masks, PEEP valves and headstraps

Disposable masks for ventilation

Model 5260
Model 5250
Model 5240
Model 5230
Model 5220
Model 5210
Model 5200
Model 5200/P



Disposable tubing

Model 1172-X
Model 1560-XXX
Model 1560/1-XXX
Model 1560-XXX-YYY
Model 1520-XXX
Model 1521-XXX-YYY
Model 1571/XXX
Model 1572/XXX

- HAR indicating that the device is supplied STERILE w/o is supplied not sterile
- XXX field indicating the different length of tubing from 30 cm to 50 mt
- YYY field indicating the different type of connectors, ventilation masks, PEEP valves and headstraps

Disposable connectors

Model 102/22X3
Model 102/22X3/TP
Model 103/22
Model 125/M
Model 125/22
Model 221/S
Model 221/S/1



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Model 1235

Model 1236

Model 1237

Model 1821

Model 1822

Model 1823

- HAR indicating that the device is supplied STERILE w/o is supplied not sterile

Disposable catheter mount

Model 114/F

Model 114/M

Model 114/FGD

Model 114/MGD

Model 115/F

Model 115/M

Model 115/FGD

Model 115/MGD

Model 116/F

Model 116/M

Model 116/FGD

Model 116/MGD

Model 117/F

Model 117/M

Model 117/FGD

Model 117/MGD

Model 118/F

Model 118/M

Model 118/FGD

Model 118/MGD

Model 119/F

Model 119/M

Model 119/FGD

Model 119/MGD

Model 120/F

Model 120/M



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Model 120/FGD

Model 120/MGD

Model 218/F

Model 218/M

Model 218/FGD

Model 218/MGD

- HAR indicating that the device is supplied STERILE w/o is supplied not sterile

Disposable anaesthesia bag

Model 411-XXX

Model 412-XXX

- HAR indicating that the device is supplied STERILE w/o is supplied not sterile
- XXX field indicating the size in liters 0,5 to 3

Accessories list

000	w/o accessory
001	Y connector with temperature port
002	Y connector with pressure port
003	Y connector with temperature and pressure port
004	Water trap 221/S
005	Catetere mount Model 115/F
006	Catetere mount Model 115/M
007	Catetere mount Model 115/FG
008	Catetere mount Model 115/MG
009	Catetere mount Model 115/FD
010	Catetere mount Model 115/MD
011	Catetere mount Model 115/FGD
012	Catetere mount Model 115/MGD
013	Catetere mount Model 116/F
014	Catetere mount Model 116/M
015	Catetere mount Model 117/F
016	Catetere mount Model 117/M
017	Catetere mount Model 118/F



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018	Catetere mount Model 118/M
019	Catetere mount Model 118/FG
020	Catetere mount Model 118/MG
021	Catetere mount Model 118/FD
022	Catetere mount Model 118/MD
023	Catetere mount Model 118/FGD
024	Catetere mount Model 118/MGD

025	Catetere mount Model 119/F
026	Catetere mount Model 119/M
027	Catetere mount Model 119/FG
028	Catetere mount Model 119/MG
029	Catetere mount Model 119/FD
030	Catetere mount Model 119/MD
031	Catetere mount Model 119/FGD
032	Catetere mount Model 119/MGD
033	Catetere mount Model 120/M
034	Catetere mount Model 120/F
035	Catetere mount Model 120/MGD
036	Catetere mount Model 120/FGD
037	Tubing Model 1520-15
038	Tubing Model 1520-30
039	Tubing Model 1520-60
040	Tubing Model 1520-90
041	Tubing Model 1520-100
042	Tubing Model 1520-120
043	Tubing Model 1520-150
044	Tubing Model 1520-180
045	Tubing Model 1560-15
046	Tubing Model 1560-30
047	Tubing Model 1560-40
048	Tubing Model 1560-50
049	Tubing Model 1560-60
050	Tubing Model 1560-80



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051	Tubing Model 1560-100
052	Tubing Model 1560-120
053	Tubing Model 1560-130
054	Tubing Model 1560-150
055	Tubing Model 1560-180
056	Tubing Model 1560-200
057	Tubing Model 1560/1-15
058	Tubing Model 1560/1-30
059	Tubing Model 1560/1-40
060	Tubing Model 1560/1-50
061	Tubing Model 1560/1-60
062	Tubing Model 1560/1-80
063	Tubing Model 1560/1-100
064	Tubing Model 1560/1-120
065	Tubing Model 1560/1-130
066	Tubing Model 1560/1-150
067	Tubing Model 1560/1-180
068	Tubing Model 1560/1-200
069	Connector Model 102/22x3
070	Connector Model 102/22x3/T
071	Connector Model 102/22x3/P
072	Connector Model 102/22x3/PT
073	Connector Model 120
074	Connector Model 120/G
075	Connector Model 125/M
076	Connector Model 1235
077	Connector Model 1236
078	Connector Model 1237
079	Connector Model 1821
080	Mouthpiece 1310
081	Connector Model 1822
082	Connector Model 1823
083	Connector valve Model 9003
084	Connector valve Model 9005



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085	Connector valve Model 9007
086	Connector valve Model 9010
087	Connector valve Model 9012
088	Connector valve Model 9015
089	Connector valve Model 9020
090	Y connector with pressure and temperature port + 1 HAR 118/MGD, 1 filter hme, 38/ASS
091	w/o tubing for humidification
092	filter BACT-HME
093	Water trap, 89/ASS, tubing 1560-60
094	1 125/22, tubing for humidification 60 cm, water trap
095	Tubing 492/ASS-300, latex free bag
096	Pediatric scavenging tubing 300 cm, 90/ASS+338/ASS, latex free bag
097	Scavenging tubing gas 120 cm
098	Scavenging tubing gas 100 cm
099	Anesthesia bag Model 412/0
100	Anesthesia bag Model 412/1
101	Anesthesia bag Model 412/2
102	Anesthesia bag modello 412/3

-
- The remaining codes 103 to 999 will be used to code combinations or variants of the various accessories. Any codes issued after number 102 are attached to this section on a special form, dated and signed by the management.



2019-05-09

HAROL

REUSABLE MEDICAL DEVICES FOR VENTILATION AND ACCESSORIES – code list Annex 4 Edit 1

11/03/2019 –
FT VENTIL HAR

Emittente:AQ

Firma: *Colleghe*

Approvato: DG

Firma: *Monica Colle*

◆ Y connectors

6102/22x3	Y connector for adult;
6102/22x3/T	Y connector with temperature port for adult;
6102/22x3/TP	Y connector with temperature and pressure ports for adult
6103/22/MF	Pediatric Y connector;
6221/S	Water trap for adult;
6221/S/1	Pediatric water trap;

◆ Straight connectors

6104/M	straight connector 15M
6104/MF	straight connector 15F
6127/22F/22	straight connector 22F-22F;
6128/22/MF	straight connector 22M-22F;
6128/22/M	straight connector 22M for adult;
6128/22/F	straight connector 22F for adult;
6129/22/M	straight connector 22M pediatric;
6129/22/F	straight connector 22F pediatric;
6137/DB	straight connector "DIGBY-LEIGH", for adult;
6137/DB/1	straight connector "DIGBY-LEIGH", for adult;

◆ Water valves

6126/27/22	Waters valve without gas scavenging connection. Complying with ISO 5356.
6126/27/E/22	Waters valve with gas scavenging connection. Complying with ISO 5356.
6126/27/E	Waters valve with gas scavenging connection. Complying with ISO 5356



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◆ Elbow connectors:

6125	elbow connector 22M-22M/15F, for adult;
6125/22	elbow connector 22F-22M/15F, for adult
6125/M	elbow connector 15M-22M/15F, for adult;

◆ "T" connectors:

DHD 235A	T connector 22M-22M/15F-22M with inspiration and expiration valve;
DHD 236	T connector 22M-22M/15F-22M;
6136/R	T connector "RUBEN" type with expiration valve

◆ Resuscitation bag

6501	Resuscitation bag RIANIMANUAL for adult
6502	Resuscitation bag RIANIMANUAL pediatric

◆ Tubing:

402-30/S	Corrugated tubing 30 cm, for adult;
402-60/S	Corrugated tubing 60 cm, for adult;
402-80/S	Corrugated tubing 80 cm, for adult;
402-100/S	Corrugated tubing 100 cm, for adult;
402-120/S	Corrugated tubing 120 cm, for adult;
402-150/S	Corrugated tubing 150 cm, for adult;
402-180/S	Corrugated tubing 180 cm, for adult;;
422-30/S	Corrugated tubing 30 cm, pediatric;
422-60/S	Corrugated tubing 60 cm, pediatric;
422-80/S	Corrugated tubing 80 cm, pediatric;
422-100/S	Corrugated tubing 100 cm, pediatric;
422-120/S	Corrugated tubing 120 cm, pediatric;
422-150/S	Corrugated tubing 150 cm, pediatric



2019-05-09

Technical File VENTIL HAR Ed. 2

Annex 3

VENTILATION DEVICE AND ACCESSORY
DECLARATION OF CONFORMITY

Issued: AQ

Signature:

Approved: DG

Signature:

Date: 02/07/2021

Manufacturer:

Harol s.r.l.
Via Marcora 53
20097 S. Donato M.se (MI)
Italy

Declare, under our responsibility, that the medical
device group:

VENTIL HAR

Type:

Disposable Breathing Circuit

Class:

Ila sterile

Reference n°:

HAR 400-YYY-ZZZ
HAR 400/1-YYY-ZZZ
HAR 401-YYY-ZZZ
HAR 401/1-YYY-ZZZ
HAR 402-YYY-ZZZ
HAR 402/1-YYY-ZZZ
HAR 403-YYY-ZZZ
HAR 403/1-YYY-ZZZ
HAR 405-YYY
HAR 405/1-YYY-ZZZ
HAR 406-YYY-ZZZ
HAR 406/1-YYY-ZZZ
HAR 1413-YYY-ZZZ
HAR1413/1-YYY-ZZZ
HAR 1615-YYY-ZZZ
HAR 1615/1-YYY-ZZZ
HAR 1616-YYY-ZZZ
HAR 1616/1-YYY-ZZZ
HAR 1617-YYY-ZZZ
HAR 1621-YYY-ZZZ
HAR 1621/1-YYY-ZZZ
HAR 1623-YYY-ZZZ
HAR 1623/1-YYY-ZZZ



Technical File VENTIL HAR Ed. 2

Annex 3

The medical device group fulfils the essential requirements of Annex I of 93/42/EEC Medical Device Directive, received through D.L. n° 46/97, as amended and certified by The Notified Body IMQ by issuing CE CERTIFICATE (Reg. 0051).

This declaration is issued in accordance with Annex VII of 93/42/EEC Medical Device Directive, as amended.

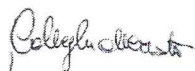
The medical device group has been developed and produced according to the following standards:

ISO 5356-1

ISO 5367

San Donato Milanese, 02/07/2021

Maria Cristina Callegher
General Manager



Technical File VENTIL HAR Ed. 2

Annex 3

VENTILATION DEVICE AND ACCESSORY
DECLARATION OF CONFORMITY

Issued: AQ

Signature:
Approved: DG

Signature:
Date: 02/07/2021

Manufacturer:

Harol s.r.l.
Via Marcora 53
20097 S. Donato M.se (MI)
Italy

Declare, under our responsibility, that the medical
device group:

VENTIL HAR

Type:

Disposable Catheter mount

Class:

Ila sterile

Reference n°:

HAR 114/YYY
HAR 115/YYY
HAR 116/YYY
HAR 117/YYY
HAR 118/YYY
HAR 119/YYY
HAR 120/YYY
HAR 218/YYY

The medical device group fulfils the essential requirements of Annex I of 93/42/EEC Medical Device Directive, received through D.L. n° 46/97, as amended and certified by The Notified Body IMQ by issuing CE CERTIFICATE (Reg. 0051).

This declaration is issued in accordance with Annex VII of 93/42/EEC Medical Device Directive, as amended.

The medical device group has been developed and produced according to the following standards:
ISO 5356-1
ISO 5367

San Donato Milanese, 02/07/2021

Cristina Callegher
General Manager

Cristina Callegher



Technical File VENTIL HAR Ed. 2

Annex 3

VENTILATION DEVICE AND ACCESSORY
DECLARATION OF CONFORMITY

Issued: AQ

Signature:
Approved: DG

Signature:
Date: 02/07/2021

Manufacturer:

Harol s.r.l.
Via Marcora 53
20097 S. Donato M.se (MI)
Italy

Declare, under our responsibility, that
the medical device group:

VENTIL HAR

Type:
Class:

Disposable breathing tube
IIa Sterile

Reference n°:

HAR 1520-YYY-ZZZ
HAR 1520/1-YYY-ZZZ
HAR 1560-YYY-ZZZ
HAR 1560/1-YYY-ZZZ
HAR 1521/1-YYY-ZZZ
HAR 1521-YYY-ZZZ

The medical device group fulfils the essential requirements of Annex I of 93/42/ECC
Medical Device Directive, received through Legislative Decree n° 46/97, as amended and
Certified by the Notify Body IMQ by issuing CE CERTIFICATE
(Reg. 0051)

This declaration is issued in accordance with Annex VII of 93/42/EEC Medical Device
Directive, as amended.

The medical device group has been developed and produced according to the following
standards:
ISO 5356-1

San Donato Milanese, 02/07/2021

Cristina Callegher
General Manager

Cristina Callegher



Technical File VENTIL HAR Ed. 2

Annex 3

VENTILATION DEVICE AND ACCESSORY
DECLARATION OF CONFORMITY

Issued: AQ

Signature:
Approved: DG

Signature:
Date: 02/07/2021

Manufacturer:

Harol s.r.l.
Via Marcora 53
20097 S. Donato M.se (MI)
Italy

Declare, under our responsibility, that
the medical device group:

VENTIL HAR

Type:
Class:

Disposable connectors
IIa sterile

Reference n°:

HAR 102/YYY
HAR 103/YYY
HAR 125/YYY
HAR 1235
HAR 1236
HAR 1237
1300
1310
HAR 18XX
HAR 90XX

The medical device group fulfils the essential requirements of Annex I of 93/42/ECC Medical Device Directive, received through Legislative Decree n° 46/97, as amended and certified by Notified Body IMQ by issuing CE CERTIFICATE (reg. 0051).

This declaration is issued in accordance with Annex VII of 93/42/EEC Medical Device Directive as amended. The medical device group has been developed and produced according to the following standards:
ISO 5356-1

San Donato Milanese, 02/07/2021

Cristina Callegher
General Manager

Cristina Callegher



Technical File VENTIL HAR Ed. 2

Annex 3

VENTILATION DEVICE AND ACCESSORY
DECLARATION OF CONFORMITY

Issued: AQ

Signature:
Approved: DG

Signature:
Date: 02/07/2021

Manufacturer:

Harol s.r.l.
Via Marcora 53
20097 S. Donato M.se (MI)
Italy

Declare, under our responsibility, that
the medical device group:

VENTIL HAR

Type:
Class:

Disposable breathing tubes
IIa

Reference n°:

1172-XXX
1520/XXX
1520/1-XXX
1560-XXX
1560/1-XXX
1571/...
1572/...

The medical device group fulfils the essential requirements of Annex I of 93/42/EEC Medical Device Directive, received through Legislative Decree n° 46/97 as amended and certified by the Notified Body IMQ by issuing CE CERTIFICATE (Reg. 0051).

This declaration is issued in accordance with Annex VII of 93/42/EEC Medical Device Directive, as amended. The medical device group has been developed and produced according to the following standards:

ISO 5356-1

San Donato Milanese, 02/07/2021

Cristina Callegher
General Manager

Cristina Callegher



Technical File VENTIL HAR Ed. 2

Annex 3

VENTILATION DEVICE AND ACCESSORY
DECLARATION OF CONFORMITY

Issued: AQ

Signature:

Approved: DG

Signature:

Date: 02/07/2021

Manufacturer:

Harol s.r.l.
Via Marcora 53
20097 S. Donato M.se (MI)
Italy

Declare, under our responsibility, that
the medical device group:

VENTIL HAR

Type:

Class:

Disposable anaesthesia masks
IIa

Reference n°:

5200/P
5200
5210
5220
5230
5240
5250
5260

The medical device group fulfills the essential requirements of Annex I of 93/42/EEC Medical Device Directive, received through Legislative Decree n° 46/97, as amended and certified by The Notified Body IMQ by issuing CE CERTIFICATE (Reg. 0051).

This declaration is issued in accordance with Annex VII of 93/42/EEC Medical Device Directive, as amended.

The medical device group has been developed and produced according to the following standards:

ISO 5356-1

San Donato Milanese, 02/07/2021

Cristina Callegher
General Manager



Technical File VENTIL HAR Ed. 2

Annex 3

VENTILATION DEVICE AND ACCESSORY
DECLARATION OF CONFORMITY

Issued: AQ

Signature:
Approved: DG

Signature:
Date: 02/07/2021

Manufacturer:

Harol s.r.l.
Via Marcora 53
20097 S. Donato M.se (MI)
Italy

Declare, under our responsibility, that
the medical device group

VENTIL HAR

Type:
Class:

Reusable manual resuscitator
IIa

Reference n°:

6501
6502

The medical device group fulfills the essential requirements of Annex I of 93/42/EEC Medical Device Directive, received through Legislative Decree n° 46/97, as amended and certified by The Notified Body IMQ by issuing CE CERTIFICATE (Reg. 0051).

The medical device group has been developed and produced according to the following standards:

ISO 5356-1

San Donato Milanese, 02/07/2021

Cristina Callegher
General Manager

Cristina Callegher



Technical File VENTIL HAR Ed. 2

Annex 3

VENTILATION DEVICE AND ACCESSORY
DECLARATION OF CONFORMITY

Issued: AQ

Signature:
Approved: DG

Signature:
Date: 02/07/2021

Manufacturer:

Harol s.r.l.
Via Marcora 53
20097 S. Donato M.se (MI)
Italy

Declare, under our responsibility, that
The medical device group:

VENTIL HAR

Type:
Class:

Reusable connector
IIa

Reference n°:

6102/YYY
6103/YYY
6104/YYY
6125/YYY
6126/YYY
6127/YYY
6128/YYY
6129/YYY
6131/YYY
6136/YYY
6137/YYY
6221/YYY
DHD235A
DHD236

The medical device group fulfills the essential requirements of Annex I of 93/42/EEC Medical Device, received through Legislative Decree n° 46/97, as amended and certified by the Notified Body IMQ by issuing CE CERTIFICATE (Reg. 0051).

This declaration is issued in accordance with Annex VII of 93/42/EEC Medical Device Directive, as amended.

The medical device group has been developed and produced according to the following standards:
ISO 5356-1

San Donato Milanese, 02/07/2021
Cristina Callegher
General Manager

Cristina Callegher



Technical File VENTIL HAR Ed. 2

Annex 3

VENTILATION DEVICE AND ACCESSORY
DECLARATION OF CONFORMITY

Issued: AQ

Signature:
Approved: DG

Signature:
Date: 02/07/2021

Manufacturer:

Harol s.r.l.
Via Marcora 53
20097 S. Donato M.se (MI)
Italy

Declare, under our responsibility, that
the medical device group:

VENTIL HAR

Type:
Class:

Anaesthesia Breathing bag
IIa sterile

Reference n°:

HAR 411-0
HAR 411-1
HAR 411-2
HAR 411-3
HAR 412-0
HAR 412-1
HAR 412-2
HAR 412-3

The medical device group fulfills the essential requirements of Annex I of 93/42/EEC Medical Device Directive, received through Legislative Decree n° 46/97, as amended and certified by the Notified Body IMQ by issuing CE CERTIFICATE (Reg. 0051).

This declaration is issued in accordance with Annex VII of 93/42/EEC Medical Device Directive, as amended.

The medical device group has been developed and produced according to the following standards:
ISO 5356-1

San Donato Milanese, 02/07/2021

Cristina Callegher
General Manager

Cristina Callegher



Technical File VENTIL HAR Ed. 2

Annex 3

**VENTILATION DEVICE AND ACCESSORY
DECLARATION OF CONFORMITY**

Issued: AQ

Signature:
Approved: DG

Signature:
Date: 02/07/2021

Manufacturer:

Harol s.r.l.
Via Marcora 53
20097 S. Donato M.se (MI)
Italy

Declare, under our responsibility, that
the medical device group:

VENTIL HAR

Type:
Class:

Reusable breathing tube
IIa

Reference n°:

402/XXX
422/XXX

The medical device group fulfills the essential requirements of Annex I of 93/42/EEC Medical Device Directive, received through Legislative Decree n° 46/97, as amended and certified by the Notified Body IMQ by issuing CE CERTIFICATE (Reg. 0051).

This declaration is issued in accordance with Annex VII of 93/42/EEC Medical Device Directive, as amended.

The medical device group has been developed and produced according to the following standards:

ISO 5356-1

San Donato Milanese, 02/07/2021

Cristina Callegher
General Manager

Cristina Callegher



Anexa 3

Nr.	nărul de catalog (referin)	Denumire generică (denumirea dispozitivului)	Denumire comercială (brand)*	Modelul	Cod GMDN*
1	1520-180-255	Mască de ventilare		pentru terapia CPAP	
2	1520-180-256	Mască de ventilare		pentru terapia CPAP	
3	1520-180-257	Mască de ventilare		pentru terapia CPAP	
4	1520-180-251	Mască de ventilare		pentru terapia CPAP	
5	5200	Mască respiratorie		pentru VAP	
6	5210	Mască respiratorie		pentru VAP	
7	5220	Mască respiratorie		pentru VAP	
8	5230	Mască respiratorie		pentru VAP	
9	5240	Mască respiratorie		pentru VAP	
10	5250	Mască respiratorie		pentru VAP	
11	5260	Mască respiratorie		pentru VAP	

