

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<br>acceptul/refuzul recepționării<br>notificării, inclusiv motivul refuzului |  |
| Data/nr. de ordine atribuit notificării<br>de către Agenție (în cazul acceptării<br>recepționării)    |  |
| Numele, prenumele, funcția<br>persoanei responsabile de<br>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. 352<sup>1</sup>, 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



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

Harol srl Via Marcora, 53 – 20097 SAN DONATO MILANESE (MI) – Tel. 02 5272788 – 02 51878215 – Fax 02 5275905

P.IVA 04566220150

e-mail: [info@harol.it](mailto:info@harol.it) – [www.harol.it](http://www.harol.it)

# 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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# HAROL

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



2019-05-09

# HAROL

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

Emittente:AQ

Firma: *Galleggi*

Approvato: DG

Firma: *Harol*

### 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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# HAROL

- 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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# HAROL

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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# HAROL

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                     |



# HAROL

|     |                              |
|-----|------------------------------|
| 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/MD  |
| 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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# HAROL

|     |                                                                                      |
|-----|--------------------------------------------------------------------------------------|
| 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: *Harol*

### ◆ 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     |



2019-05-09

# HAROL

## ◆ 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.

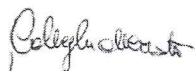
The medical device group has been developed and produced according to the following standards:

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

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



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          |           |

