

**HARSORIA™  
FLOW REGULATOR**

# INSTRUCTIONS FOR USE

**MATERIAL USED:**

- ABS, PVC, HDPE, PP, POLYCARBONATE (PC) & POLY ISOPRENE

**INDICATIONS:**

- Graduated infusion of I.V. Solutions
- Intravenous drugs administration
- Total Parenteral Nutrition (TPN)

**CONTRAINDICATIONS:**

- Product should not be used in patients with known hypersensitivity to any of the materials used
- Administration of high viscous fluids
- Cannot be used for blood transfusion

**INSTRUCTIONS FOR USE:**

- The connecting port of this device is in compliance to EN 20594-1 & ISO 594-2
- Connect flow regulator input to IV set/bag
- Release clamp on IV set to allow fluid to flow through
- Prime flow regulator with 10-20 ml
- Re-clamp proximal (input) tube
- Connect output tube to IV access
- Set desired flow rate by rotating graduated marker and also by drop counting in drip chamber of I.V. Set
- Note drop size from packing of IV set; flow regulator has a tolerance of ±10% in flow rates
- Release clamp to allow fluid flow
- Observe for adequate flow

**TERM OF USE :**

- Recommended Maximum Duration of Use: Depends on type of medication and other factors; refer to your facility's guidelines or CDC Guidelines

**WARNINGS:**

- The use of this product is restricted to a qualified doctor or a Paramedic
- Read instructions before use
- The product should be used according to the instructions for use
- If there is any change in expected performance of the device or in case of any malfunction the device should be immediately removed & sent back to supplier for analysis
- **For known/reported adverse events associated with use of this device, refer to the Clinical Evaluation Report HH-QA-CER-FR**
- **HARSORIA HEALTHCARE DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE**
- Any device that is connected to this product must comply with EN 20594-1 & ISO 594-2 in order to achieve the intended performance of this product & to avoid leakage in this connection
- The product should not be reprocessed
- Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural and/or functional damage to device or packaging
- The product is guaranteed sterile & non-pyrogenic if the package has not been opened or damaged
- Do not clean or re-sterilise. For single use only. Discard after use
- Re-use of this device may change its mechanical or biological features and may cause device failure, allergic, reactions or infections
- **Disposal/Discard:** Dispose off/Discard the used Device in accordance with your Country's Healthcare and Safety Regulations



Product Ref. No.



Batch Number



Date Of Manufacturing



Use By



Do Not Reuse



Sterilised by Ethylene Oxide Gas



Caution, Consult  
Accompanying Documents



Consult Instructions  
For Use



Non-Pyrogenic



Do Not Use if  
Package is Damaged

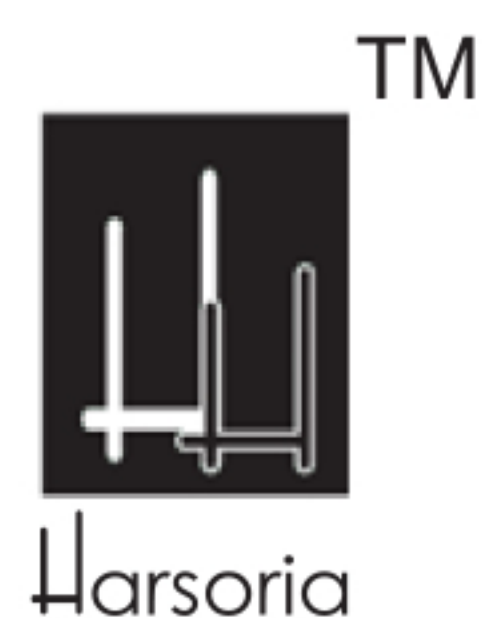


Do not re-sterilize



Keep away  
from sunlight

DEHP  
Free



Manufactured By:  
**HARSORIA HEALTHCARE PVT. LTD.**  
110 -111, Phase-IV, Udyog Vihar,  
Gurgaon - 122 015, Haryana, INDIA.  
Email: info@harsoria.com  
Website: www.harsoria.com  
Customer Care No.: +91 124 4523400

**EC REP**  
mdi Europa GmbH  
Langenhagener Str. 71  
D-30855 Langenhagen  
Email: info@mdi-europa.com

**CE 2460**

Lic. No.: MFG/MD/2019/000135  
AW/IFU\_E2, Rev. 10  
Rev. Date:04.09.2019



**HARSORIA™  
FLOW REGULATOR**

# INSTRUCTIONS FOR USE

**MATERIAL USED:**

- ABS, PVC, HDPE, PP, POLYCARBONATE (PC) & POLY ISOPRENE

**INDICATIONS:**

- Graduated infusion of I.V. Solutions
- Intravenous drugs administration
- Total Parental Nutrition (TPN)

**CONTRAINDICATIONS:**

- Product should not be used in patients with known hypersensitivity to any of the materials used
- Administration of high viscous fluids
- Cannot be used for blood transfusion

**INSTRUCTIONS FOR USE:**

- The connecting port of this device is in compliance to EN 20594-1 & ISO 594-2
- Connect flow regulator input to IV set/bag
- Release clamp on IV set to allow fluid to flow through
- Prime flow regulator with 10-20 ml
- Re-clamp proximal (input) tube
- Connect output tube to IV access
- Set desired flow rate by rotating graduated marker and also by drop counting in drip chamber of I.V. Set
- Note drop size from packing of IV set; flow regulator has a tolerance of  $\pm 10\%$  in flow rates
- Release clamp to allow fluid flow
- Observe for adequate flow

**TERM OF USE :**

- Recommended Maximum Duration of Use: Depends on type of medication and other factors; refer to your facility's guidelines or CDC Guidelines

**WARNINGS:**

- The use of this product is restricted to a qualified doctor or a Paramedic
- Read instructions before use
- The product should be used according to the instructions for use
- If there is any change in expected performance of the device or in case of any malfunction the device should be immediately removed & sent back to supplier for analysis
- **For known/reported adverse events associated with use of this device, refer to the Clinical Evaluation Report HH-QA-CER-FR**
- **HARSORIA HEALTHCARE DISCLAIMS ANY RESPONSIBILITY FOR POSSIBLE CONSEQUENCES RESULTING FROM IMPROPER USE**
- Any device that is connected to this product must comply with EN 20594-1 & ISO 594-2 in order to achieve the intended performance of this product & to avoid leakage in this connection
- The product should not be reprocessed
- Visually inspect and carefully check the product and packaging before use. Improper transport and handling may cause structural and/or functional damage to device or packaging
- The product is guaranteed sterile & non-pyrogenic if the package has not been opened or damaged
- Do not clean or re-sterilize. For single use only. Discard after use
- Re-use of this device may change its mechanical or biological features and may cause device failure, allergic, reactions or infections
- **Disposal/Discard:** Dispose off/Discard the used Device in accordance with your Country's Healthcare and Safety Regulations



Product Ref. No.



Batch Number



Date Of Manufacturing



Use By



Do Not Reuse



Sterilised by Ethylene Oxide Gas



Caution, Consult  
Accompanying Documents



Consult Instructions  
For Use



Non-Pyrogenic



Do Not Use if  
Package is Damage



Do not re-sterilize



Keep away  
from sunlight

DEHP  
Free



Manufactured By:  
**HARSORIA HEALTHCARE PVT. LTD., UNIT-2**  
KK 83/85, Kh.No.: 342/266  
Saraj Majra Gujran, Jharmajri Road  
Baddi - 173205, Distt.: Solan, (H.P.) India  
Website: www.harsoria.com  
Customer Care No.: +91 124 4523400

Mfg. Lic. No: MFG/MD/2018/000093

AW/IFU\_E2d, Rev. 00  
Rev. Date: 31.07.2019