



## Harsoria Healthcare Pvt. Ltd.

(A 100% Export Oriented Unit)

110-111, Phase-IV, Udyog Vihar, Gurgaon, Haryana-122 015, INDIA

Tel.: +91-124-5010 172-73 Fax: +91-124-2397 114

Email: info@harsoria.com

Website: www.harsoria.com



The certification body of QS quality service confirm that we,

**HARSORIA HEALTHCARE PVT.LTD**

**110-111, Phase, Udyog Vihar, Gurgaon, Haryana – 122 015, India**

have establish and are maintaining a quality management system according to

**ISO 13485: 2003/ NS-EN ISO 13485: 2012/ ISO 9001:2008**

For the following area

**Design and Manafacture of Sterial Medical devices for Intravenous Therapy and Monitoring**

Furthermore we have implemented the conformity assessment procedure as per annex II module H of the Medical Device Directive 93/42/EEC (EC certificate No. 5262 – 2014- CE- IND- NA)

We, **HARSORIA HEALTHCARE PVT.LTD**

confirm,

that we follow the essential requirements according to MDD 93/42/EEC Annex I for attached list.

India, 11<sup>th</sup> July 2017

For Harsoria Healthcare Pvt. Ltd.

  
(Neeraj Gupta)  
Managing Director



GIÁM ĐỐC  
Vũ Hoàng Việt





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Attachment to Declaration

### List of Medical devices

1. IV Cannula with Catheter with or without injection valve and with or without wings
2. Safety IV Cannula with Catheter with or without injection valve and with or without wings
3. AV Fistula Needle Set
4. Injection Stopper
5. 3 Way Stop Cock with/without Extension Tubes
6. Extension Tube
7. Flow Regulator
8. Luer Cap
9. Combi Luer Lock
10. Intravenous Infusion Set (I.V. Set)
11. Blood Transfusion Set (B.T. Set)
12. Central Venous Catheter kit
13. Hemodialysis Catheter kit

