

CERTIFICATE OF VERIFICATION



INTERNATIONAL CERTIFICATION SERVICES PVT. LTD.

This is to certify that the products of

**UDAIPUR HEALTH CARE PVT. LTD.**

Regd. Office: 155, Chetak Marg, Udaipur – 313 001, Rajasthan, India.

Factory: Village Dakan Kotada, Salumber Road, Udaipur – 313 001,  
Rajasthan, India.

Registered as complying with safety requirements of EC Directives: Medical Device Directive 2007/47/EC Directive

**PRODUCT**

**Plaster Of Paris Bandage, Synthetic Casting Bandage And Elastic Bandage.**

Registration No. : RP91/6160  
Registered Date : 28<sup>th</sup> July, 2012  
Reassessment Date : 13<sup>th</sup> August, 2018  
Issue Date : 07<sup>th</sup> September, 2018  
Expiry Date : 27<sup>th</sup> July, 2021



Technical Statement:

The TCF is, in so far as is Technically Viable, based on inspection and testing Harmonized European Standards provided all safety measures are followed.

1. Medical Device Directive 2007/47/EC , (93/42/EEC), Harmonized Standards: ISO 13485:2016, ISO 14971:2009, ISO 15223:2000 and B.P and IS 16111:2013
2. ICS CE Assessment Report No. RC2/RP91/6160/2018/06/04 dated 17.06.2018.
3. Paralab Pvt. Ltd., Test Report No. No.A0615/005/18 Dated 20.06.18, A0615/006/18 Dated 20.06.18 & A0615/007/18 Dated 20.06.18, K0201/026/17 Dated 01.02.2017, D0505/005/16 Dated 12.05.2016
4. Manufacturer's EC Declaration of Conformity signed on 17.06.2018.

Managing Director  
International Certification Services Pvt. Ltd.

Validity of this certificate is based on periodic audits of the EC Directive defined by the Technical statement and its contingent upon prompt, written notification of significant changes to the EC Directive and/or its components thereof shall be immediately communicated to ICS.

Registration No. : RP91/6160



**(Polyester substrate)**

S.No.	Product Code	Color	Size(Width x Length)	Intermediate Packing (Rolls /Inner Box)	Final Packing (Rolls /Shipper Carton)
1	Durocast Poly 2"	White	5cm x 360cm	10	100
2	Durocast Poly 3"	White	7.5cm x 360cm	10	100
3	Durocast Poly 4"	White	10cm x 360cm	10	100
4	Durocast Poly 5"	White	12.5cm x 360cm	10	100
5	Durocast Poly 2"	Blue	5cm x 360cm	10	100
6	Durocast Poly 3"	Blue	7.5cm x 360cm	10	100
7	Durocast Poly 4"	Blue	10cm x 360cm	10	100
8	Durocast Poly 5"	Blue	12.5cm x 360cm	10	100
9	Durocast Poly 2"	Green	5cm x 360cm	10	100
10	Durocast Poly 3"	Green	7.5cm x 360cm	10	100
11	Durocast Poly 4"	Green	10cm x 360cm	10	100
12	Durocast Poly 5"	Green	12.5cm x 360cm	10	100
13	Durocast Poly 2"	Yellow	5cm x 360cm	10	100
14	Durocast Poly 3"	Yellow	7.5cm x 360cm	10	100
15	Durocast Poly 4"	Yellow	10cm x 360cm	10	100
16	Durocast Poly 5"	Yellow	12.5cm x 360cm	10	100
17	Durocast Poly 2"	Pink	5cm x 360cm	10	100
18	Durocast Poly 3"	Pink	7.5cm x 360cm	10	100
19	Durocast Poly 4"	Pink	10cm x 360cm	10	100
20	Durocast Poly 5"	Pink	12.5cm x 360cm	10	100

**Elastic Bandage**

S. No.	Product Code	Color	Size(Width x Stretched Length )	Intermediate Packing (Rolls /Inner Box)	Final Packing (Rolls /Shipper Carton)
1	Elastic Bandage 2	White	2 cm x 2 to 4 m.	12	120
2	Elastic Bandage 3	White	3 cm x 2 to 4 m.	12	120
3	Elastic Bandage 4	White	4 cm x 2 to 4 m.	12	120
4	Elastic Bandage 5	White	5 cm x 2 to 4 m.	12	120
5	Elastic Bandage 6	White	6 cm x 2 to 4 m.	12	120
6	Elastic Bandage 7	White	7 cm x 2 to 4 m.	12	120
7	Elastic Bandage 8	White	8 cm x 2 to 4 m.	12	120
8	Elastic Bandage 9	White	9 cm x 2 to 4 m.	12	120
9	Elastic Bandage 10	White	10 cm x 2 to 4 m.	12	120
10	Elastic Bandage 11	White	11 cm x 2 to 4 m.	12	120
11	Elastic Bandage 12	White	12 cm x 2 to 4 m.	12	120
12	Elastic Bandage 13	White	13 cm x 2 to 4 m.	12	120
13	Elastic Bandage 14	White	14 cm x 2 to 4 m.	12	120
14	Elastic Bandage 15	White	15 cm x 2 to 4 m.	12	120



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**PLASTER OF PARIS BANDAGE**

S. No.	Product Code	Size(Width x Length)	Intermediate Packing (Rolls /Inner Box)	Final Packing Rolls per Shipper Case
1	POP15	15 cm x 2.7 m	10	120
2	POP10	10 cm x 2.7 m	10	120
3	POP075	7.5 cm x 2.7 m	10	120
4	POP20	20 cm x 2.7 m	8	80
5	POP5	5 cm x 2.7 m	10	120

**Synthetic Casting Bandage**

**( Fiberglass substrate)**

S. No.	Product Code	Color	Size(Width x Length)	Intermediate Packing (Rolls /Inner Box)	Final Packing (Rolls per Shipper Carton)
1	Durocast 2"	White	5cm x 360cm	10	100
2	Durocast 3"	White	7.5cm x 360cm	10	100
3	Durocast 4"	White	10cm x 360cm	10	100
4	Durocast 5"	White	12.5cm x 360cm	10	100
5	Durocast 6"	White	15cm x 360cm	10	100
6	Durocast 2"	Blue	5cm x 360cm	10	100
7	Durocast 3"	Blue	7.5cm x 360cm	10	100
8	Durocast 4"	Blue	10cm x 360cm	10	100
9	Durocast 5"	Blue	12.5cm x 360cm	10	100
10	Durocast 6"	Blue	15cm x 360cm	10	100
11	Durocast 2"	Green	5cm x 360cm	10	100
12	Durocast 3"	Green	7.5cm x 360cm	10	100
13	Durocast 4"	Green	10cm x 360cm	10	100
14	Durocast 5"	Green	12.5cm x 360cm	10	100
15	Durocast 6"	Green	15cm x 360cm	10	100
16	Durocast 2"	Yellow	5cm x 360cm	10	100
17	Durocast 3"	Yellow	7.5cm x 360cm	10	100
18	Durocast 4"	Yellow	10cm x 360cm	10	100
19	Durocast 5"	Yellow	12.5cm x 360cm	10	100
20	Durocast 6"	Yellow	15cm x 360cm	10	100

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