

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 2017/745 EC Directive

PRODUCT

Scope : Plaster Of Paris Bandages, Elastic Bandages, Synthetic Casting Bandage And Under Cast Padding.

Registration No.	: RP91/6160
Registered Date	: 28 th July, 2012
Reassessment Date	: 05 th August, 2024
Issue Date	: 12 th August, 2024
Expiry Date	: 27 th July, 2027



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. EC Directive: Medical Device Directive 2017/745, Harmonized Standards: ISO 13485:2016, ISO 14971:2019, ISO 15223:2000 and B.P and IS 16111:2013 and IS 16303:2014.
2. ICS CE Assessment Report No. RP91/6160/2024/07/04 dated 24.07.2024.
3. Paralab Pvt. Ltd.- Test Report No. No. DO617/008/21 Dtd. 22.06.21, DO617/007/21 Dtd. 26.06.21 & DO617/006/21 Dated 24.06.21, DO617/009/21 Dated 24.06.21 & SRF – QA/SOP/08 Dtd.28.06.21 & DO5041027/23 Dtd. 08.05.23.
4. Manufacturer's EC Declaration of Conformity signed on 22.07.2024.

Director (Technical)
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.