

Declaration of Conformity

Manufacturer: BAP Medical B.V.
Laan van Westenenk 64
7336 AZ, Apeldoorn
The Netherlands

Manufacturer SRN: NL-MF-000002030

Contract manufacturer: Aruba Aloe Balm Inc.
Pitastraat 115
Oranjestad
Aruba

Product: **ALHYDRAN** product range

Product identification: Basic UDI-DI – 5425013000116PB
See appendix I for tradenames and product UDI-DI

Risk class: **Class 1** Medical Device, based on rule 4 of Annex VIII

We, BAP Medical BV, hereby declare and confirm that the products of the ALHYDRAN product range that are covered by this declaration are in conformity with EU regulation 2017/745 .

This declaration of conformity is issued under the sole responsibility of BAP Medical B.V. and supported by the Quality System certification based on ISO 13485:2016, quality system certificate with reference number 11448, KIWA_NV_HC-M, first issued on 1 November 2010, delivered by KIWA CERMET ITALIA, SpA.

This declaration is no longer valid if any change on the products will be made without our written confirmation.

Date, February 14th 2022




BAP Medical B.V.
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Irene Körbl
RA/QA Manager
BAP Medical B.V.

Appendix I

| PRODUCT TRADENAME | PRODUCT CODE | PACKAGING | UDI-DI |
|--------------------------------|--------------|----------------|----------------|
| ALHYDRAN | 20-20003 | 3 ml (sample) | 05425013000123 |
| ALHYDRAN | 20-10015 | 15 ml | 05425013000130 |
| ALHYDRAN | 20-20015 | 15 ml (sample) | 05425013000109 |
| ALHYDRAN | 20-20030 | 30 ml | 05425013000017 |
| ALHYDRAN | 20-20059 | 59 ml | 05425013000079 |
| ALHYDRAN | 20-20100 | 100 ml | 05425013000024 |
| ALHYDRAN | 20-20250 | 250 ml | 05425013000031 |
| ALHYDRAN SPF | 20-20003spf | 3 ml (sample) | 05425013000147 |
| ALHYDRAN SPF | 20-20059spf | 59 ml | 05425013000048 |
| ALHYDRAN Anti Itch Care | 20-31050 | 59 ml | 05425013009997 |
| ALHYDRAN Barrier Repair Care | 20-32050 | 59 ml | 05425013000062 |
| ALHYDRAN Cracked Dry Skin Care | 20-33050 | 59 ml | 05425013009904 |
| ALHYDRAN Eczema Care | 20-34050 | 59 ml | 05425013000055 |

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