

EU – Declaration of Conformity

We, the company,

Beiersdorf AG
SRN DE-MF-000014151

20245 Hamburg
Germany

hereby declare in our sole responsibility as legal manufacturer that the devices

48800-00000-46	HP HDR_REG STR 6 PCS DE_EN
48800-00001-46	HP HDR_REG STR 6 PCS DE_FR_NL
48800-00002-46	HP HDR_REG STR 6 PCS IT_PT
48800-00003-46	HP HDR_REG STR 6 PCS EL_ES
48800-00004-46	EPL HDR_REG STR 6 PCS EN
48800-00005-46	EPL HDR_REG STR 6 PCS EN_FR
48800-01030-46	HP HDR_REG STR 6 PCS INT
48800-03010-46	CURI HDR_REG STR 6 PCS ES
48802-00000-46	HP HDR STR XL 3 PCS DE_EN
48802-00001-46	HP HDR STR XL 3 PCS DE_FR_NL
48802-00002-46	HP HDR STR XL 3 PCS INT
48802-00004-46	EPL HDR STR XL 3 PCS EN
48802-00005-46	EPL HDR STR XL 3 PCS EN_FR
48802-01050-46	HP HDR STR XL 3 PCS ID
48802-03010-46	CURI HDR STR XL 3 PCS ES
98000-00042-00	HYDRO HP/EPL/CURI INT. SAMPLING

Product Identification: Hansaplast® / Elastoplast® / Curitas® Hydrocolloid plaster
Basic-UDI-DI: 400580000000000000000065DB
Intended Use: Protection and treatment of minor wounds such as scratches, cuts and abrasions.
 Prevention and treatment of blisters, pressure spots and friction marks.

are in compliance with Regulation (EU) 2017/745 concerning medical devices.

Classification

according to Annex VIII of the Regulation (EU) named above.

Class IIa (rule 4)

Conformity Assessment Procedure

according to Annex IX chapter I and III of the Regulation (EU) named above.

Beiersdorf	Beiersdorf international documentation system BEC.10264435.000.03 DoC Hydrocolloid Plaster	Released: 17.12.24-... Page 2 of 2
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Notified Body

DEKRA Certification GmbH

Handwerkstraße 15
70565 STUTTGART
Germany

Notified Body number: 0124

EU Certificate no. 50533-60

This declaration remains valid also in case the above-mentioned EU Certificate for the Quality Management System of Beiersdorf AG is renewed or revised.

This declaration is also valid for products which may carry additional labels to comply with local market and regulatory requirements (relabeling).

Hamburg (Germany), 17.12.2024



Maren Gerhard
Senior Regulatory Affairs Manager
(Signed for and on behalf of Beiersdorf AG)