

Beiersdorf	Beiersdorf international documentation system BEC.10259491.000.02 DoC Fast Healing MDR	Released: 15.08.24-... Page 1 of 2
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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 device(s)

45629-00000-48	HP FST_HLG 65X43 TR 8 DE_FR_IT A
45629-00000-49	HP FST_HLG 65X43 TR 8 DE_FR_IT
45629-00001-48	HP FST_HLG 65X43 TR 8 INT A
45629-00004-48	EPL FST_HLG 65X43 TR 8 EN A
45629-00014-48	EPL FST_HLG 65X43 TR 8 FR A

Product Identification:	HPL AQP Fast Healing / EPL Waterproof Fast Healing
Basic-UDI-DI:	40058000000000000000051CY
Intended Use:	Wound plaster to cover and protect minor wounds/ Covering and protection of minor everyday wounds / Covering and protection of minor everyday wounds such as abrasions, scratches, cuts and grazes. / suitable for abrasions.

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 (excluding chapter II) of the Regulation (EU) named above.

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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)

15.08.2024
(date)


René Seitz

Senior Regulatory Affairs Manager

(Signed for and on behalf of Beiersdorf AG)