

Beiersdorf	Beiersdorf international documentation system BEC.10245895.000.07 DoC Wound Spray Forward	Released: 28.07.23-... Page 1 of 2
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We,

Beiersdorf AG

20245 Hamburg
Germany

are exclusively responsible for this declaration of conformity and hereby declare, that the following products
(article number refers to the smallest sales unit of the product)

48387-00000-45	HP WND_SPY PHMB 0.04% 15ML DE
48387-00001-45	HP WND_SPY PHMB 0.04% 15ML IT
48387-00002-45	CURI WND_SPY PHMB 0.04% 15ML ES
48387-00003-45	HP WND_SPY PHMB 0.04% 15ML ES
48388-00000-45	HP WND_SPY PHMB 0.04% 50ML DE
48388-00000-48	HP WND_SPY PHMB 0.04% 50ML DE
48388-00001-45	HP WND_SPY PHMB 0.04% 50ML DE_FR_IT
48388-00003-45	EPL WND_SPY PHMB 0.04% 50ML EN
48388-00004-45	EPL WND_SPY PHMB 0.04% 50ML FR
48388-00004-48	EPL WND_SPY PHMB 0.04% 50ML FR
48388-00005-45	CURI WND_SPY PHMB 0.04% 50ML ES
48388-00008-48	HP WND_SPY PHMB 0.04% 50ML EN_ES_MS
48388-00006-45	HP WND_SPY PHMB 0.04% 50ML DE EUROHANGER
48388-00007-45	HP WND_SPY PHMB 0.04% 50ML DE_FR_NL
48388-00007-47	HP WND_SPY PHMB 0.04% 50ML DE_FR_NL
48388-00008-45	HP WND_SPY PHMB 0.04% 50ML ES
48388-00009-45	EPL WND_SPY PHMB 0.04% 50ML EN
48388-00011-45	HP WND_SPY PHMB 0.04% 50ML DE_FR_NL
48389-00000-45	HP WND_SPY PHMB 0.04% 100ML DE_FR_NL
48389-00000-47	HP WND_SPY PHMB 0.04% 100ML DE_FR_NL
48389-00000-48	HP WND_SPY PHMB 0.04% 100ML DE_FR_NL
48389-00002-45	HP WND_SPY PHMB 0.04% 100ML PT
48389-00002-47	HP WND_SPY PHMB 0.04% 100ML ES_PT
48389-00003-45	HP WND_SPY PHMB 0.04% 100ML EL_IT
48389-00004-45	HP WND_SPY PHMB 0.04% 100ML AR_EN_MS
48389-00005-45	HP WND_SPY PHMB 0.04% 100ML INT
48389-00006-45	EPL WND_SPY PHMB 0.04% 100ML EN
48389-00009-45	EPL WND_SPY PHMB 0.04% 100ML EN
48389-00010-45	HP WND_SPY PHMB 0.04% 100ML DE_FR_NL
48390-00001-45	HP WND_SPY_KDS PHMB 0.04% 100ML DE_FR_NL
48390-00001-47	HP WND_SPY_KDS PHMB 0.04% 100ML DE_FR_NL
48390-00001-48	HP WND_SPY_KDS PHMB 0.04% 100ML DE_FR_NL
48390-00002-45	HP WND_SPY_KDS PHMB 0.04% 100ML EL_ES
48390-00002-47	HP WND_SPY_KDS PHMB 0.04% 100ML EL_ES_PT
48390-00003-45	HP WND_SPY_KDS PHMB 0.04% 100ML DE_FR_NL
48759-00000-45	HP WND_SPY PHMB 0.04% 250ML DE

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within the

class IIb

comply with

Medical Device Directive 93/42/EEC, annex I.

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

Conformity assessment procedure follows

Medical Device Directive 93/42/EEC, annex II.

Notified Body for Conformity Assessment Procedure:

DEKRA Certification GmbH
Handwerkstraße 15
70565 STUTTGART
Country: Germany

Notified Body number: 0124

EC-Certificate Number: 50533-16

20253 Hamburg (Germany)
(place of issuance)

28.07.2023
(date)


Martina Fraenkel
Senior Regulatory Affairs Manager

Expiry date of this document:
valid until 26.05.2024

Beiersdorf	Beiersdorf international documentation system BEC.10245895.001.03 Annex to DoC Wound Spray Forward	Released: 28.08.24-... Page 1 of 1
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We,

Beiersdorf AG

20245 Hamburg

are exclusively responsible for this annex to the declaration of conformity and hereby declare, that according to

REGULATION (EU) 2023/607 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 15 March 2023
amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for
certain medical devices and in vitro diagnostic medical devices

the validity of the declaration of conformity BEC.10245895.000.07 for Wound Spray Forward (BEA.10245890) is extended until 31.12.2028.

The following products (article number refers to the smallest sales unit of the product) are added to the product list of the valid declaration of conformity according to the requirements listed the in the above stated regulation:

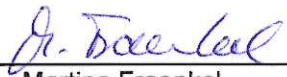
48388-03010-49	CURI WND_SPY PHMB 0.04% 50ML ES
48389-00002-48	HP WND_SPY PHMB 0.04% 100ML ES_PT
48389-00005-47	HP WND_SPY PHMB 0.04% 100ML INT

The following documents are valid in addition to this annex to the declaration of conformity:

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|---|---------------------|
| • DoC Wound Spray Forward | BEC.10245895.000.07 |
| • MDR Manufacturer Declaration BDF | CDC.20003102.000.01 |
| • DEKRA Confirmation Letter | CDC.20003104.000.01 |
| • Certificate QA - Annex II (50533-16-06) | CDC.20002236.000.01 |
| • Annex to the EC Certificate 50533-16-06 | CDC.20002236.100.01 |

20245 Hamburg (Germany)
(place of issuance)

28.08.2024
(date)


Martina Fraenkel
Senior Regulatory Affairs Manager