**Beiersdorf** 

# Beiersdorf international documentation system BEC.10246009.000.03 DoC Wound Healing Ointment MDR

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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)

48383-00000-46	HP WND_HLG_OIN 20G DE
48383-00001-46	HP WND_HLG_OIN 20G ES_PT
48383-00002-46	HP WND_HLG_OIN 20G IT
48383-00003-46	HP WND_HLG_OIN 20G ID
48383-00004-46	EPL WND_HLG_OIN 20G EN
48383-00005-46	EPL WND_HLG_OIN 20G FR
48383-00006-46	CURI WND_HLG_OIN 20G ES
48383-00007-46	HP WND_HLG_OIN 20G DE EUROHANGER
48383-00008-46	HP WND_HLG_OIN 20G DE_FR_NL
48383-00009-46	HP WND_HLG_OIN 20G INT
48383-00010-46	HP WND_HLG_OIN 20G DE
48384-00000-46	HP WND_HLG_OIN 50G DE_FR_IT
48384-00001-46	HP WND_HLG_OIN 50G DE_FR_NL
48384-00002-46	HP WND_HLG_OIN 50G EL_PT
48384-00003-46	HP WND_HLG_OIN 50G AR_EN_MS
48384-00004-46	EPL WND_HLG_OIN 50G EN
48384-00005-46	HP WND_HLG_OIN 50G DE_FR_NL
48384-00006-46	EPL WND_HLG_OIN 50G EN_FR

Product Identification:

Hansaplast/Elastoplast/Curitas Wound Healing Ointment

Basic-UDI-DI:

40058000000000000000043CZ

Intended Use:

Intended to support the healing of minor, superficial wounds

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

#### Classification

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

class lla (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), 31.7.2024

(date)

René Seitz

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