



EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III
(Class IIa and Class IIb Devices)

No. G10 011858 0065 Rev. 01

Manufacturer:

PAUL HARTMANN AG

Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s).

The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:G10 011858 0065 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:G10_011858_0065_Rev.01)

Report No.:	713162860
Preceding Certificate No.:	G10 011858 0065 Rev. 00
Valid from:	2020-12-17
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Issue date: 2020-12-17

C s
Head of Certification/Notified Body



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No. G10 011858 0065 Rev. 01

Classification: IIb
Device Group: M040499 - DRESSINGS FOR WOUNDS, SORES AND
 ULCERATIONS - OTHERS

Intended Purpose: Single-use, sterile, non-medicated dressings suitable for the
 treatment of wounds

**The validity of this certificate
 depends on conditions and/or
 is limited to the following:** -

Revision History:	Rev.	Dated	Report
	00	2020-05-06	713162860