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TÜV SÜD Product Service GmbH • Ridlerstraße 65 • 80339 Munich • Germany

To whom it may concern

Munich, 2021-02-02
Order No.: 713206847_3

Confirmation concerning Certificates G1 011858 0064 Rev. 00, G2S 011858 0063 Rev. 00 and related devices

We confirm the following certificates:

G1 011858 0064 Rev. 00 (valid until 2024-05-26)
G2S 011858 0063 Rev. 00 (valid until 2024-05-26)

issued to the legal medical device manufacturer:

PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY

cover the Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4) with the scope (G1 011858 0064 Rev. 00):

Medical devices for general and special wound treatment, operating theatre products, bandages and tapes, patient care products for use on the ward and in general practice as well as medical devices with a measuring function. (Class IIa and IIb medical devices)

and the following devices:

Product name	Product group
HydroTac Border Multisite	4.02 Hydroactive dressings and accessories
Zetuvit Plus Silicone Border	4.02 Hydroactive dressings and accessories
RespoSorb Silicone Border	4.02 Hydroactive dressings and accessories

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and cover the Directive 93/42/EEC on Medical Devices Annex V with the scope (G2S 011858 0063 Rev. 00):

Medical devices for general and special wound treatment, operating theatre products, bandages and tapes, patient care products for use on the ward and in general practice as well as products with special purposes. (Class I sterile medical devices)
Systems and procedure packs according to Article 12 of Directive 93/42/EEC

and the following device

Product name	Product group
Cosmopor I.V. transparent	2.05 Adhesive dressings

Further we confirm an implemented quality assurance system for manufacture of devices in class I in sterile conditions, sterilized systems or procedure packs listed in the scope of the above-mentioned EC-Certificate (G2S 011858 0063 Rev. 00) and its attachments.

With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.

The above-mentioned certificate is valid.

R. Köhler

MÜNCHEN TÜV SÜD PRODUCT SERVICE

i.A. Randolf Köhler
TÜV SÜD PRODUCT SERVICE GMBH
Medical Health Services
Foreign Affairs

Product Service

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To whom it may concern

Munich, 2021-01-26
Order No.: 713206847_2

Confirmation concerning Certificate G2S 011858 0063 Rev. 00 and related device

We confirm the following certificate:

G2S 011858 0063 Rev. 00 (valid until 2024-05-26)

issued to the legal medical device manufacturer:

PAUL HARTMANN AG
Paul-Hartmann-Str. 12
89522 Heidenheim
GERMANY

covers the Directive 93/42/EEC on Medical Devices Annex V with the scope:

Medical devices for general and special wound treatment, operating theatre products, bandages and tapes, patient care products for use on the ward and in general practice as well as products with special purposes. (Class I sterile medical devices)
Systems and procedure packs according to Article 12 of Directive 93/42/EEC

and the following device

Product name	Product group
Cosmopor I.V. transparent	2.05 Adhesive dressings

Further we confirm an implemented quality assurance system for manufacture of devices in class I in sterile conditions, sterilized systems or procedure packs listed in the scope of the above-mentioned EC-Certificate and its attachments.

With this letter we confirm that the above-mentioned devices are covered by a quality assurance system that has been established by the manufacturer and is certified by the notified body TÜV SÜD Product Service GmbH.

After issuing the declaration of conformity in accordance with the medical device directive 93/42/EEC by the manufacturer, the above-mentioned medical devices can be labelled with CE mark (CE 0123) and placed on the market in the European Economic Area.
The above-mentioned certificate is valid.

i.A. Randolf Köhler
TÜV SÜD PRODUCT SERVICE GMBH
Medical Health Services
Foreign Affairs

MÜNCHEN TÜV SÜD PRODUCT SERVICE