

FIELD SAFETY NOTICE

Brand name: Equispon, Equicel and Equitamp

FSCA #: 01/2023 (Equispon)

02/2023 (Equicel and Equitamp)

Problem description: Counterfeit Medical Device "Equispon"

In March 2023 the Health and Youth Care Inspectorate (NL) received a compliance and enforcement request (CEF) from Agentia Nationala a Medicamentului si a Despozitivelor Medicale din Romania (Romanian Competent Authority) concerning falsified certificates on Equispon. The medical devices manufactured before May 2019 could be still on the market as the expiration date is in 2024, and they are NOT counterfeiting. The medical devices counterfeiting are not manufactured by Equimedical BV and are covered by falsified CE certificates, with expiry date 20.04.2026 and for the site "Equimedical Haemostats, SL - Spain" that no longer exists.

Given that:

the medical devices manufactured before May 2019 are NOT counterfeiting and can be used.

Maastricht, 13.07.2023, Rev.1

Equimedical BV
Quality Assurance Manager
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