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Non-regulatory press release

ColdZyme® certified under the new EU medical device regulation (MDR)

Enzymatica's mouth spray ColdZyme® has received CE-certification under the new and more demanding European Union medical device regulation (MDR). This important milestone validates the company's scientific data and extends product claims throughout the EU. The certification is a key pillar for expansion in several markets and is expected to have long-term positive effects on Enzymatica's growth.

Eurofins, a European approved notified body for medical devices, has certified the ColdZyme® product line MDR (class III) according to the European Union medical device regulation. MDR replaces the previous EU regulation MDD and imposes stricter requirements on evidence of clinical validity, safety design, and market surveillance. ColdZyme is one of the first flu- and cold products to be certified under the new regulation.

"This is an important milestone in the history of Enzymatica as the MDR certification validates our scientific data and creates great commercial opportunities for us. In addition, it increases the consumer confidence in ColdZyme® as well as opens up new markets. The certification is highly anticipated by our partners since it ensures long term security which will contribute to Enzymatica's growth," says Claus Egstrand, CEO of Enzymatica.

Eurofins has reviewed full data including safety, efficacy, and product claims. ColdZyme® has maintained the highest MDR classification, class III, during the process and both intended use and product claims are now able to expand due to the MDR-certification.

"This certification process has meant extensive review of our quality processes and product data in accordance with the medical device legislation. Our expanded, verified health claims will now help us to communicate ColdZyme's benefits and efficacy even more clearly towards customers, retailers, and partners," says Ann-Christine Provoost, Director Regulatory Affairs.

ColdZyme® MDR certification

ColdZyme® provide an effective barrier that protects the oral cavity and throat and creates an osmotically active transient barrier that traps viruses deactivates and inhibits the viruses' ability to bond, deactivating their ability to infect cells. ColdZyme® products are now MDR certified with the following expanded intended use:

- Treat and relieve cold and flu-like symptoms.

and with the following expanded product claims:

- Protects against viruses that cause cold and flu-like infections of the upper respiratory tract.
- Shortens the duration of cold and flu-like upper respiratory tract infections if used at an early stage of the infection.
- Relieves cold and flu-like symptoms, including sore throat.

For more information, please visit https://coldzyme.co.uk/

About MDR

The Medical Device Regulation (MDR) is an EU regulation to ensure the safety and performance of medical devices.

- MDR stands for Medical Device Regulation, an EU regulatory framework for medical devices that applies within the EU.
- It aims to improve patient safety by introducing stricter methods of assessment and market surveillance.
- The MDR applies as of May 26th, 2021.
- The MDR aims to ensure and improve patient safety and the performance of medical devices in the EU.

Read more

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References:

1. Eccles R. Understanding the symptoms of the common cold and influenza. Lancet Infect Dis. 2005 Nov;5(11):718-25.

About Enzymatica
Enzymatica AB develops and sells products that treat and alleviate infections and symptoms in the upper respiratory tract. The products are based on the Penzyme® technology, which includes marine enzymes with unique properties. The best-selling product is ColdZyme®, a mouth spray for colds and cold-like symptoms of the upper respiratory tract. ColdZyme has been launched in over 30 markets on four continents. The strategy is to continue to grow by developing more health products, strengthening the company's position in existing markets and expanding into new geographic markets through established partners. The company is headquartered in Lund and is listed on Nasdaq First North Growth Market. Enzymatica's certified advisor is Carnegie Investment Bank AB (publ). For more information please visit www.enzymatica.com.