

24 April, 2020

ColdZyme re-certified to class III in the EU

Enzymatica's common cold spray ColdZyme® has been re-certified under the Council Directive 93/42/EEC (MDD) by the notified body Eurofins Product Testing. Thereby, ColdZyme will have a CE marking of the highest class, which implies that the product can be sold as a class III medical device within the EU until May 2024. ColdZyme and its documentation have been reviewed by Eurofins, which is an organization designated by a Competent authority for certification of medical devices within the EU. Eurofins has reviewed the complete documentation for ColdZyme including data for safety, efficacy and product benefits.

The re-certification process has covered a re-classification of ColdZyme from class I to class III. The background to the re-classification is a change of the interpretation of animal tissue, which is based on the fact that ColdZyme contains an enzyme (trypsin) derived from the atlantic cod (*Gadus morhua*). In this process, the intended use and product benefits have been reviewed and approved with respect to clinical efficacy and safety documentation. According to the re-certification by Eurofins the intended use is: 'to treat and alleviate common cold', and with the following product benefits:

- ColdZyme protects against common cold viruses.
- ColdZyme can help shorten the duration of a common cold if used at an early stage of the infection.
- ColdZyme alleviates common cold symptoms and soothes sore throat.

"This is a very gratifying notification. Eurofins has performed an extensive review of both Enzymatica's processes and the documentation for ColdZyme, and found that the product meets the requirements for a CE marking class III. Thus, pre-clinical data, clinical data, production processes and quality system have been reviewed and found to correspond with the requirements of the highest classification for medical device products within the EU, which is a clear quality stamp and increases the trust for our common cold spray on an international level," says Fredrik Lindberg, CEO of Enzymatica.

FOR MORE INFORMATION, PLEASE CONTACT:

Fredrik Lindberg, CEO Enzymatica AB

Phone: +46 (0)708-86 53 70 | Email: fredrik.lindberg@enzymatica.com

Carl-Johan Wachtmeister, Communication manager Enzymatica AB

Phone: +46 (0)701-88 50 21 | Email: carl-johan.wachtmeister@enzymatica.com

ABOUT ENZYMATICA AB

Enzymatica AB is a Swedish life science company that develops and sells health care products for primarily conditions of the ear-nose-and-throat region. The products are based on a barrier technology that includes marine enzymes. The company's first product is the medical device ColdZyme®, a mouth spray against common cold. The product has been launched in about ten markets. The strategy is to continue to grow by developing more health care products and strengthening the company's position in existing markets and expanding into new geographic markets through established partners. The company has its headquarters in Lund and is listed on Nasdaq First North Growth Market. For more information, visit: www.enzymatica.com and www.enzymatica.se/en/section/media/press-releases

Enzymatica's certified adviser is Erik Penser Bank. Phone: +46 (0)8 463 83 00. Email: certifiedadviser@penser.se

Enzymatica AB (publ)

Ideon Science Park, SE-223 70 Lund, Sweden

Tel: +46 (0)46-286 31 00, Web: enzymatica.se