

Press release  
Lund 5 DEC 2019

## Scandinavian ChemoTech AB changes Notified Body for CE marking

***Due to a large demand on European Notified Bodies, ChemoTech has not been able to obtain the agreed audit from its contracted notified body within the agreed time. ChemoTech has therefor chosen to sign a new agreement with Ente Certificazione Macchine (ECM). A Notified Body is an organisation designated by an EU country to assess the conformity of certain products before being placed on the market.***

The EU regulations for medical technology companies will change significantly from May 2020. The upcoming regulatory change for CE marking has created a great demand from already certified companies to extend their current certificates. The Notified Body that ChemoTech has contracted has in this situation prioritised already certified companies, which is why ChemoTech chooses to change its Notified Body.

“In this extended process we are now pleased to announce that we have now received a notified body that has been able to grant us an audit date. Since our technical file already is completed, it will immediately be handed over to ECM”, says Mohan Frick, CEO of ChemoTech.

The first audit will take place before the end of February 2020 followed by ECM reviewing all documentation and tests of the IQwave before the final audit and certification takes place.

Since all third-party tests of IQwave have already been completed and approved, this means that IQwave meets all EN60601 standards for electrical safety and electromagnetic compatibility. These tests are part of the technical file that ECM will review.

### **About Ente Certazione Macchine**

Ente Certazione Macchine, ECM has been supporting companies since 1996 to verify compliance with the standards set in several EU directives. ECM is a Notified Body and accredited testing laboratory that offers many options for quality and safety related services. ECM offers CE certification, MDR Gap analysis, QMS ISO 13485 & 9001 certification, MDR training, test lab service and Fast Service for CE and ISO.

*For more information, please contact:*

Mohan Frick, CEO  
+46 (0)10-218 93 00  
[info@chemotech.se](mailto:info@chemotech.se)

*This information is such information which Scandinavian ChemoTech AB (publ) are obligated to make public according to EU's market abuse regulation. The information was submitted by*

*the agency of above stated contact person, to be made public on Monday the 9<sup>th</sup> of December 2019 at 11.45 (CET).*

### **Scandinavian ChemoTech AB (publ)**

ChemoTech is a Swedish medical technology company based in Lund that has developed a patented technology platform to offer cancer patients access to a new treatment alternative, tumour specific electroporation, available for treatment of both for humans and animals. There are a large number of cancer patients whose tumours for various reasons cannot be treated by conventional methods but where tumour specific electroporation can be a solution. Therefore, the company continuously evaluates new opportunities and areas of application for the technology. ChemoTech's shares (CMOTEC B) are listed on Nasdaq First North Growth Market in Stockholm and Västra Hamnen Corporate Finance AB is the company's Certified Adviser. Read more at: [www.chemotech.se](http://www.chemotech.se).