ICTRECHT

ZIVVER is not required to apply CE-marking
Date: July, 2020

**ICTRecht B.V.**
Jollemanhof 12
1019 GW Amsterdam

TELEFOON
020 663 1941

E-MAIL
info@ictrecht.nl

INTERNET
ictrecht.nl

KVK
34216164

BTW
NL822330040B01

IBAN
NL07 RABO 0325 2813 78

LOCATIES

NEDERLAND
Amsterdam
Groningen

BELGIË
Brussel

ZIVVER is a secure communication platform with the goal to provide organizations and users the comfort of safe communication. The platform and its end-user applications supports secure sharing of messages, images and all other types of files between users, users to guests (person using ZIVVER with person not using ZIVVER), guests to user and to and from systems via different out-of-the-box interfaces including SMTP or via the ZIVVER-API.

The ZIVVER platform is also used in the healthcare industry. In this respect, it is of importance to determine whether ZIVVER's platform can be considered a 'medical device' within the meaning of the Medical Device Direction (hereinafter: *'MDD'*) and as a result thereof should adhere to the provisions of the MDD.[1] If the latter is the case, it would also be mandatory to apply CE (*Conformité Européenne*)-marking to the ZIVVER platform.

Under the MDD, software is only considered a 'medical device' if the intended purpose of the manufacturer corresponds to the medical purposes referred to in the MDD. Medical purposes include diagnosis, monitoring and treatment in the context of healthcare. The communication platform of ZIVVER is not a medical device under the MDD. ZIVVER performs no actions with a medical purpose on those messages and files. ZIVVER only secures and safely delivers these messages and files.

Supporting the above, it is of relevance that a guidance has been written by the European Commission in this respect.[2] The guidance provides concrete tools to assess whether software can be considered as a medical device. It is explicitly stated that communication systems used in healthcare (e.g. email, mobile telecommunication and video communication) are intended for general purposes when the software is used to send both medical and non-medical information. In addition, the guidance concludes that systems that are intended to store, archive or transfer data do not qualify as a medical device. The communication platform of ZIVVER is only used for such general purposes and helps storing and transferring ad-hoc data.

In light of the above, it can be concluded that the communication platform of ZIVVER is not a medical device and therefore does not require to apply any CE-marking.

Note that, although the legislation is subject to change (where the directive will be replaced by a regulation), The communication platform of ZIVVER will also not fall under the definition of a medical device under the Medical Device Regulation,

[1] Medical Device Directive 93/42/EEC.
[2] Meddev 2.1/ July 2016.

which will enter into force on 26 May 2021.[3] Because the new guidance drawn up by the Medical Device Coordination Group follows the current approach.[4]

[3] Medical Device Regulation (EU) 2017/745.
[4] MDCG 2019-11/ October 2019.