HANTSON
law firm

Henegouwenstraat 41
9000 Ghent
09 225 40 45

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To Mr F. Gelaude
Unmatched
Sint-Jorisstraat 96 8730
Beernem

BY E-MAIL

Our REF.: 2019/0612/Unmatched - LynX®
Your REF.: LynX®

Dear Mr Gelaude,

I come back to your request for advice of last January 9th, when you asked me whether or not the LynX® software is a medical device and whether it has to obtain a CE mark.

LynX® is an alarm server that is intended to be used by healthcare institutions, amongst others. The alarm server´s software detects incoming alarm messages originating from a wide range of devices and equipment (personal alarms, classic panic buttons, reanimation systems, electrodes of automatic defibrillators, medical wearables, and so on). The devices and equipment to which LynX® is linked can be both medical and non-medical in kind. After detection of the alarm messages,[1] the alarm server immediately determines which care giver the relevant alarm should be sent to, and the message is passed on to the right person(s).

I am happy to inform you that the LynX® software – as it exists today, in its current version – is *not* a medical device, and therefore a CE mark is not required. Below I explain this position on the basis of the applicable regulations, in particular the Medical Device Directive (MDD)[2] and the Medical Device Regulation (MDR)[3].

[1] The alarm messages that are sent out by devices and equipment other than LynX®.

[2] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, O.J. 12 July 1993, issue 169, 1-43.

[3] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, and repealing Council Directives 90/385/EEC and 93/42/EEC, *O*.J. 5 May 2017, issue 117, 1-175.

1. THE MEDICAL DEVICE DIRECTIVE AND THE MEDICAL DEVICE REGULATION

All medical devices that are put on the market in Europe currently have to meet the Medical Device Directive. A certain prudence is called for here. The Medical Device Regulation entered into effect on 25 May 2017. This regulation replaces the Medical Device Directive.

Note carefully that the Medical Device Regulation provides for a transitional measure, under which medical devices only have to comply with the new rules of the Medical Device Regulation by 26 May 2020 at the latest.[4] Of course, manufacturers of medical devices can already voluntarily make their products conform to the Medical Device Regulation. They don´t have to wait until the effective application date of 26 May 2020 to bring their product into accordance with the Medical Device Regulation. Obviously, manufacturers that meet the new regulation before 26 May 2020 can already put their product onto the European market earlier.[5][5]

Although the effective application date of the Medical Device Regulation may still seem relatively far off, it would nevertheless be wise to prepare a transition well in advance so that the medical devices comply with this regulation.

2. LYNX® IS NOT A MEDICAL DEVICE UNDER THE MEDICAL DEVICE REGULATION

Before bringing the LynX® software into conformity with the Medical Device Regulation, we must ask whether this regulation actually applies to this particular product. Or, to put it another way: does LynX® really fall within the scope of application of the Medical Device Regulation?

For LynX® to fall within the scope of application of the Medical Device Regulation, it would have to be a "medical device". A medical device is defined as:

> *" (…) software (…) intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific purposes: diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,investigation, replacement or modification of the anatomy or of a physiological or pathological process or state, providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended*

[4] Article 1 (2) and article 123 of the Medical Device Regulation.
[5] Article 120 (5) of the Medical Device Regulation

action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means."[6]

From this it can be deduced that the essential issue is what purpose the manufacturer gives to the software. Thus the *intended use* of a manufacturer is important. For software to be regarded as a medical device, it is essential that the manufacturer give a specific medical purpose to this software, such as: the diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of a disease, an injury or a disability.

In this case, the LynX® alarm server is presently a pure communication platform, and not a medical device. The LynX® software works in such a way that it exclusively detects alarm messages from other devices and equipment and forwards these messages, as necessary, to the responsible contact person who has been designated in advance. LynX® has in this respect no medical functionalities, but can be regarded as an intermediary channel of communication. The LynX® software *per se* is not intended for clinical decision-making within the framework of a specific disease, injury or disability. The LynX® software *per se* is also not intended for monitoring a disease, injury or disability per se. Nor is this software intended for preventive, diagnostic or therapeutic purposes.

With regard to the effect of the alarm server, moreover, within the framework of the medical device regulations it is not important whether for the software there is a direct effect in or on the human body. Nor is it important that the software is used in a medical context. After all, it isn´t the environment in which the software is used that is relevant, but rather the purpose thereof. Thus, software used for general purposes in a healthcare setting is not a medical device.[7]

The above line of reasoning is also supported by two decisions of the Court of Justice of the European Union: the *Brain Products* decision of 22 November 2012[8] and the *Snitem* decision of 7 December 2017[9]. In these two decisions, the Court asserts that a medical device must be intended for use in humans for purposes of the diagnosis, prevention, monitoring, treatment or alleviation of diseases, or

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[6] Article 2, *sub* 1) of the Medical Device Regulation

[7] J. HANTSON, "*In welke mate kan standalonesoftware aangewend in het kader van mobiele gezondheidszorg (mHealth) worden gekwalificeerd als een medisch hulpmiddel dat voorzien moet zijn van CE-markering?*" [To what extent can stand alone software used in the framework of mobile healthcare (mHealth) be characterised as a "medical device" that must obtain a CE mark?], *T.Gez.* 2018, issue 5, 310-313, note under ECJ (4th chamber) 7 December 2017.

[8] ECJ 22 November 2012, *Brain Products v BioSemi VOF et al*., no. C-219/11.

[9] ECJ 7 December 2017, *Syndicat national de l'industrie des technologies médicales (Snitem) and Philips France v Premier ministre and Ministre des Affaires sociales et de la Santé*, C-329/16.

the diagnosis, monitoring, treatment, alleviation or compensation for an injury or handicap. Moreover the Court asserts in these decisions that one can only speak of a "medical device" when the software can create or modify medical information, in particular by means of calculation, quantification or comparison of the recorded data against certain references.

The Court bases itself for this on the MEDDEV guideline 2.1/6.[10.11] *In this case* we find that the LynX® software actually does not create or modify any medical information. The only thing the software does is sort and forward information (*i.e.* an alarm message) to the person(s) involved. In this respect the LynX® software is an intermediary channel of communication of signals, because the signals themselves are not modified in any way.

3. LYNX® IS NOT AN ACCESSORY FOR AN ALREADY-EXISTING MEDICAL DEVICE UNDER THE MEDICAL DEVICE REGULATION

The Medical Device Regulation also applies to accessories for medical devices. An accessory for a medical device is:

> "*an article which, whilst not being itself a medical device, is intended by its manufacturer to be used together with one or several particular medical device(s) to specifically enable the medical device(s) to be used in accordance with its/their intended purpose(s) or to specifically and directly assist the medical functionality of the medical device(s) in terms of its/their intended purpose(s);*."[12]

In other words, an accessory for a medical device is itself a device that is intended to support the performances of one or more of the parent medical devices. An accessory for a medical device is in fact an add-on or an attachment.

In this case, LynX® is a general platform that - in an independent and autonomous manner - can host a large number of applications, including an alarm server. LynX® thus does not form an integral part of already-existing devices and equipment to which it is linked. The devices and equipment to which LynX® are linked work perfectly well without it, even without the intermediary intervention of LynX®

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[10] European Commission, MEDDEV 2.1/6, *Guidelines on the qualification and classification of stand alone software used in healthcare within the regulatory framework of medical devices*, July 2016.

[11] A certain prudence is recommended in any case. MEDDEV guidelines do not constitute a position officially adopted by the European Commission. The guidelines of the MDCG [Medical Device Coordination Group] are therefore not legally binding and only the European Court of Justice can give a binding interpretation of the Union law. Moreover, at present it is still unclear whether the MEDDEV 2.1/6 will continue to be valid after the effective entry into force of the Medical Device Regulation. On its website, the European Commission has stated on this that all "*guidance and implementing measures*" will be revised in the coming years on the basis of the new regulation.

[12] Article 2, *sub* 2) of the Medical Device Regulation.

being required. This means that when the LynX® software is linked to devices and equipment that are regarded as medical devices, LynX® does not fall under the CE mark of these medical devices.

It is interesting to also refer to the possible collaboration with Itémedical. Given that the software of Itémedical, i.e. "MediScore MDDG", does have a medical functionality *and* interprets medical information, MediScore MDDG is naturally a medical device. The fact that MediScore MDDG should in the near future be linked to LynX® of course has no effect on the fact that LynX® is not a medical device. Nevertheless, the collaboration between MediScore MDDG and LynX® can constitute a beneficial synergy for both manufacturers, with favourable implications for the customers.

4. A FUTURE UPGRADE OF LYNX® CAN GIVE RISE TO A MEDICAL DEVICE IN ACCORDANCE WITH THE MEDICAL DEVICE REGULATION

From the above explanation it appears that LynX®, today, is not a medical device and consequently does not have to comply with the medical device regulations. Nevertheless it would be wise to take a proactive stance. Our conversations made clear that the intention is - through the implementation of artificial intelligence with algorithmic decision-making - to expand the functionalities of the LynX® software in the near future. For example, you mentioned (amongst other things) the introduction of data location and the interpretation of clinical data for various medical purposes. Such an upgrade of the software would naturally result in an adaptation of the *intended use* of LynX®. This means that LynX® as of that point might well be regarded as a medical device, as a result of which the software would have to be brought into full compliance with the Medical Device Regulation.

From our conversations it appears that, considering the future expansion of the functionalities of LynX®, you are prepared to make this software compliant with the Medical Device Regulation. As discussed, I can assist and support you on this. For the sake of completeness, I note that with this added functionality in that case you would have to bring LynX into compliance with the Medical Device Regulation.

5. CONCLUSION

At present, the LynX® alarm server is *not* a medical device. This means that this software does not fall within the scope of application of the Medical Device Regulation, and therefore a CE mark is not required.

Note carefully, however: if in the future the software of LynX® is upgraded by the addition of medical functionalities, then the LynX® alarm server might well be regarded as a medical device. In that case, the software shall fall within the scope of application of the Medical Device Regulation, and a CE mark will be required. You would then still have until 26 May 2020 to bring the software into compliance with this regulation.

If you have any questions, don´t hesitate to contact me.

Kind regards,

Julie Hantson