

"Lasers in dentistry are on a good way with a great market potential. Even such an incident by an individual manufacturer will not change this."

NMT Senior Consultant Joachim Koop comments on the current legal dispute between NMT and Syneron Dental Laser. Interview by Georg Isbaner. Leipzig, 17 August 2012.



_laser: Dear Mr Koop, in the year 2009 your company started to market dental laser systems made by Syneron. These are meant to be systems

with trailblazing technology, which you distributed with tremendous success from scratch.

Trailblazing laser technology is complemented in this case with the consulting, sales and training competence in your company. It also meant a great opportunity to enter into a new promising partnership with new impulses that had long been awaited by many in the dental laser market.

Since the end of last year the situation has turned when a legal dispute between the manufacturer, you as the distributor of Litetouch products and the dentists harmed ensued. What happened?

If an accredited certification body, that furthermore has its seat in Germany, issues a CE certificate for a medical device, all market players should have the right to trust the certificate that the product really meets the certification requirements.

The ordering of a suspension of a certificate issued in 2007 raises many questions that the responsible manufacturer Syneron has not yet adequately responded to.

I would never have thought this is possible for such a big and up to now very renowned laser manufacturer like Syneron that operates worldwide and is listed on the Stock Exchange. _How did you find out about the increased EMC radiation that led to the suspension of the CE certificate?

The corresponding indications came from a former sales partner of Syneron in Italy. The company, Creation, represented by Prof Resch, during an attempt to get a CE admission for an OEM product on the basis of Litetouch, did not get permission due to increased EMC values which are practically identical with the currently measured values of the original product.

This happened—as we know only today—in the year 2009. Prof Resch correspondingly also informed the German officials and, among others, the trade supervisory board in Munich. Despite all placatory letters by Syneron, the company went on to deny facts even in December 2011, which led to an official order end of January 2012 to suspend the CE license.

This was definitely not a voluntary attempt on behalf of Syneron. An incredible case—unique in its way.

_Are the examination and certification procedures insufficient?

In Germany and the EU there are no general pointers to underline this hypothesis. In my view, there is no such case.

_May the dentists continue treating their patients with their Litetouch?

With the current product on the market, we expressly recommend not to do that—however, very much so with the new product which is now, after almost seven months, used in exchange for the device with our customers—one after the other and in a sequence that is not comprehensible.

_What does it mean for your company?

Thank God only very few users have tried to file any claims against us because it is clear to every-body who is solely responsible for this situation. Our customers supported us in our endeavour to find out and make progress with the manufacturer for the benefit of the customer. What is more, we filed suit with the public prosecutor against Syneron and the responsible representatives, because it is important that all wronged parties find out about the true circumstances. The result of the public prosecutor investigations is of great importance also for NMT. This is why the six doctors affected filed their own demands for prosecution.

_May the laser devices still be sold?

The former device may no longer be sold within the European Economic Area of the EU—due to the

official decree confirming their non-applicability without a CE certification.

What does the manufacturer do?

The conduct of Syneron Dental after the loss of the CE certificate seems almost worse than the loss itself. Many months went by without any attempt to limit the damage, without any appropriate compensation offer for the long non-operation of the laser therapy during daily therapy—a completely insufficient information policy.

To me, this conduct is incomprehensible with regard to a formerly highly respected manufacturer of high-calibre laser technology.

_Does this new technology still have a market? The basic idea of this new technology was and has been irresistible. The device put on the market by Syneron obviously was not ready for the market; this is shown by the new heavy hand pieces of the products to be exchanged. In my view, the development will be driven forward and lead to success in the future.

_Which solutions do you offer to the customers concerned?

We recommend to all to accept the exchange of the instruments by Syneron, without waiving any claims for damages at this very time. Damages may also be claimed at a later time, depending on the outcome of the public prosecutor investigations.

A future better alternative is already available with the laser systems of Biolase, the world market leader of dental laser systems. Only with the help of this experienced manufacturer was it possible for NMT to overcome the dispute and finally emerge stronger from this ongoing legal dispute with Syneron.

Lasers in dentistry are on a good way with great application and market potential. Even such an unbelievable and irresponsible incident by an individual manufacturer will not change this.

Mr Koop, thank you for this interview!

_contact

NMT Neue Medizintechnik München GmbH

laser

Flurstraße 5

82166 Gräfelfing, Germany

info@nmt-muc.de www.nmt-muc.de