



Milano 02.08.2016

To Mrs Elena Santiago CID
Director General
CEN-CENELEC Management Center (CCMC)
Avenue Marnix 17 – 1000 Brussels, Belgium
esantiago@cencenelec.eu

Dear Mrs Santiago

As the representative of ASSECE (Associazione Europea di Chirurgia Estetica) I have been informed about the soon to be published European Standard EN 16708 Beauty Salon Services which allows non-medical personnel (beauticians) to **deliver medical procedures**.

This is absolutely unacceptable because it implies an obvious risk for the patient, and we urgently request that you review and/or remove the following treatments from the Beauty Salon Standard as listed on Anex A. table B.1:

Chemical peels: here, under “equipment and instruments” it states that “Beauty therapists shall only use professional branded preparations that conform to the European Cosmetic Regulation (EC No1233/2009)”. But such regulation doesn’t mention safety limits for concentration or pH for the peelings used in beauty salons. Such conditions are paramount to determine the depth of action of a product, and hence it’s safety. So unless it is rephrased, this means that it is the manufacturer who determines what product shall be used in beauty salons. We think that leaving such duty in the hands of the industry, whose main concern are the sales, is a danger to patients.

Laser/IPL treatment: the document states that beauty therapists can, un-supervised, use IPL and even class 3b and 4 lasers. We must point out how dangerous this is. Laser treatment has many reported risks worldwide and the only way to minimize them is through a careful diagnostic of each patient, and a thorough knowledge of the physiology of the skin and of photodynamics. Several international publications warn of the dangers of such procedures when there is no medical supervision. One from USA published in a peer reviewed journal reported the risk of laser hair removal and that 85% of the laser complications reported occurred in establishments that had no medical supervision. In this point we firmly request that laser treatments have to be done under medical

supervision and that means the doctor has to be in the facility at the time of the treatment so as to determine the right parameters to be used and capable of delivering immediate treatment in case of complication.

Aesthetic treatments gone wrong



epilation laser



IPL epilation



epilation laser



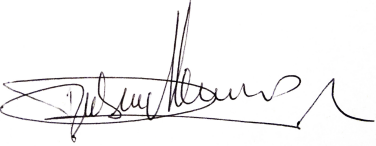
Radiofrequency: Just like laser devices, radiofrequency has evolved during the last years with many new devices ranging from rather harmless low-power devices to high power devices with effects reaching and severely wounding the deep dermal and subcutaneous compartment. Hence, side-effects may involve not just superficial, but also deep tissue (third degree burn, which is the gravest). If these techniques should be used by beauticians, there should be a clear distinction between devices that are relatively safe to use by beauty salon professionals and devices with higher risk of side effects. This could eventually be based on the depth of the target tissue treated.

Micro-needling: it is most shocking to find **mesotherapy** included in this point. We must point out that the word mesotherapy relates to a means of administering a drug. It is the same as saying intravenous, intramuscular, etc. in this case the drug is delivered into the mesodermal layer of the skin. It might seem that in this standard the word mesotherapy has been used as a synonym for microneedling, but they are two very distinct treatments and the confusion is dangerous. Mesotherapy, as the drug delivery technique it is, has potential risks, in as much that in France the government even considered banning it because of the number of complications caused by an inappropriate technique. The word mesotherapy must be erased from the beauty salon standard to avoid misleading patients and because of the grave risk that would derive.

All the treatments listed above are considered potentially harmful to patients' health and should not be included in a Beauty Salon Services standard as it doesn't cover the adequate environment and training to perform this kind of treatments.

We as the European Association of Aesthetic Surgery are very worried and ask you to take appropriate steps and withdraw this standard till it has been amended.

Kind regards

A handwritten signature in dark ink, appearing to read 'Ruben Oddenino', is written over a light blue horizontal line. The signature is fluid and cursive, with a large initial 'R'.

Prof. Dr. Ruben Oddenino, M.D.
President of ASSECE
(Associazione Europea di Chirurgia Estetica)
- European Association of Aesthetic Surgery -