APPLiA
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Industry Guide for Good IPL Practices

Recognise Safe and Functional Intense Pulsed Light (IPL) Devices for Hair Removal at Home

This guide aims to empower consumers to make informed purchasing decisions and contribute to a safer market environment. It also seeks to raise awareness among Competent Authorities about their responsibility for safeguarding the Transition Provisions of EU Medical Device Regulation 1. Specifically, EU Common Specifications 2022/2346, article 2, point 1 or 2: a) the product was already lawfully marketed in the Union before 22 June 2023 and continues to comply with the requirements of Union and national law that were applicable to it before 22 June 2023; b) there are no significant changes in the design and intended purpose of the product.

IPL devices should meet specific requirements, including **having a CE mark, a Declaration of Conformity, electrical safety certification, instructions of use in local languages, and accessible manufacturer information.** Under the EU Medical Device Regulation (MDR), additional features outlined in EU Common Specifications are expected. While some IPL devices already comply with these stringent safety requirements, others do not. We advise consumers, manufacturers, and economic operators to differentiate IPL devices based on state-of-the-art safety and functionality features listed below:

- **Integrated skin tone sensor(s) – no flashing or significantly reduced energy on darker skin tones (ref. Fitzpatrick scale)**: The applicable EN standard (IEC 60335-2-113:2016) does not mandate a skin tone sensor, relying on a colour chart. Differently, the Common Specifications require an integrated skin tone sensor to assess the skin patch near the treatment area. Several manufacturers have already developed and included this sensor.
- **Skin contact detection sensor(s) to flash only if in full skin contact**: The applicable EN standard requires 'good contact with the skin' whereas the Common Specifications state: 'include continuous contact controls and an interlock system ensuring that the device works only in case of full skin contact with the emitting area of the device'. The industry standard technology for a skin detection sensor is a capacitive sensor whereas mechanical sensors are still allowed, risking full skin contact and thus an increased chance of flashing in the air.
- **Clinically proven effectiveness**: EU MDR mandates that manufacturers must provide clinical evidence to demonstrate the safety and performance of their devices for the intended use (hair removal for home use IPLs).

Conclusion

To protect consumers, it is important to differentiate IPL devices by state-of-the-art safety features. These features include skin tone and skin detection sensors, as well as the requirement for clinical data to demonstrate safety/efficacy. Enforcement of the Common Specifications' transitional provisions is necessary to ensure a level playing field during the transitional period (22 June 2023 - 31 Dec 2028/2029). Competent Authorities are expected to safeguard this fairness.

[1] Intense Pulsed Light (IPL) Devices for Hair Removal is classified as medical device (without a medical purpose) due to similarity of IPL with medical devices in terms of functioning and risk profile, according to the Regulation EU 2017/745 MDR – Annex XVI as of 22 June 2023 with a transition period by EU Common Specifications (2022/2346, as amended by 2023/1194). It means that lawfully marketed IPL devices before 22 June 2023 can continue to be placed or put into service to the EU market until 31 Dec 2028 (or 31 Dec 2029 if manufacturer conducts a Clinical Investigation) while continue to be compliant with EU Directives and harmonised standards relevant with Household electrical appliances (such as Low Voltage Directive, Electromagnetic Compatibility Directive etc.) if no significant changes in the design and the intended purpose.