



PRESS RELEASE
Brussels, Belgium
5th April 2017

EUROMCONTACT WELCOMES THE ADOPTION BY THE EUROPEAN PARLIAMENT OF THE MEDICAL DEVICES REGULATION THAT WILL NOW ALLOW FOR PUBLICATION IN THE OFFICIAL JOURNAL. THE MDR STRENGTHENS THE PLACING OF THE MARKET OF MEDICAL DEVICES, INCLUDING CONTACT LENSES AND INCLUDES ADDITIONAL REQUIREMENTS REGARDING POST-MARKET SURVEILLANCE. FOR THE CONTACT LENS SECTOR, THE MDR INCLUDES IN ITS SCOPE NON-CORRECTIVE CONTACT LENSES, WHICH IS WELCOMED BY THE INDUSTRY.

On 5th April 2017, the European Parliament adopted at its plenary meeting the new Regulation on Medical Devices (MDR). This is the last step in the legislative process for the formal adoption of the MDR, which is expected to be published in the Official Journal early May. The MDR will enter into force 3 years after the date of application, i.e. in spring 2020.

For the contact lenses sector, this new regulation is a modernisation of the original rules, bringing together best practices from existing Commission guidance. With a tight three-year transition period, the areas where industry has highlighted as priority for agreed harmonised approaches and clarity are the transition provisions, the updated clinical evaluation requirements, and the early availability of notified bodies.

Euromcontact, representing the Contact Lens industry, welcomes the new MDR. The new regulatory framework will strengthen the requirements for CE marking of medical devices and the requirements regarding post-market surveillance. The MDR also provides for a traceability system to be put in place for medical devices. In particular Euromcontact welcomes the inclusion of plano contact lenses (the so-called cosmetic lenses) in the scope of the new regulation, a change which has been supported by the Industry for many years to protect the safety of patients and contact lens wearers. Euromcontact will support its members in implementing the new regulation, and will continue to engage with the legislators to provide input in the legal acts that will support the MDR.

Helmer Schweizer, President of Euromcontact stated *"Euromcontact is committed to continue its engagement with the European decision-makers, especially when the technical discussions on common specifications and other delegated acts will take place and where the expertise and competence of the industry could be needed and of value."*

EUROMCONTACT is the voice of European contact lens and lens care industry to the European Institutions, media, stakeholders and the public. EUROMCONTACT is the European Federation of National Associations and International Companies of Contact Lens and Lens Care Manufacturers. EUROMCONTACT members include National Associations of Manufacturers, representing Netherlands, Germany, Italy, Spain, Switzerland and the United Kingdom; the global companies Alcon, Abbott, Bausch & Lomb, Ciba Vision, CooperVision, Johnson & Johnson Vision Care, Menicon; Mark'ennovy and the European Federation for the Contact Lens Industry EFCLIN.

ENDS

For further information, please contact:

Pascale Rouhier

Secretary General EUROMCONTACT aisbl

10, rue de Tamines

1060 Brussels-BE

Phone/Fax : +32 2 537 37 11

Pascale.rouhier@euromcontact.eu - www.euromcontact.eu