

Safety Notice

Medical Devices

Hy-Care® Multipurpose Contact Lens Care Solutions

Priority 1 – For Immediate Action



HPRA Safety Notice: SN2022(02)

Issue Date: 3rd March 2022

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
CooperVision Manufacturing Limited	V50423

ISSUE

CooperVision Manufacturing Ltd is conducting a worldwide consumer level recall of all un-expired Hy-Care® contact lens solutions after it became aware that these contact lens solutions may not offer appropriate levels of disinfection in some circumstances against high levels of a particular yeast organism.

CooperVision Manufacturing Ltd has issued a number of Field Safety Notices (FSN) for the various stakeholder groups in order to inform all users of this issue. Please refer to accompanying FSN1 for information for Eye Care Practitioners and an FAQ for the dedicated patient recall website, and refer to accompanying FSN2 for notices relating to distributors.

The manufacturer has advised to cease use and dispose of any affected product as instructed in the FSN.

The HPRA understands that supply in Ireland is via opticians/optometrists, however there may also be online sales of these products.

The HPRA has not received any reports of adverse incidents associated with this issue from the Irish market and is issuing this Safety Notice to raise awareness of this recall.

Please see the accompanying FSNs and the manufacturer's dedicated recall website (<https://www.cvrecall.expertinquiry.com/>) for further details.

ACTION OR RECOMMENDATIONS

The HPRA advises that **distributors / opticians / optometrists / retailers:**

1. Refer to the accompanying FSNs and follow the instructions provided by CooperVision Manufacturing Ltd.
2. Follow the instructions in the relevant FSN to identify whether you have affected devices at your facility.
3. If so, immediately quarantine and discontinue sale of the affected products.
4. Ensure that affected devices are disposed of according to the instructions provided by the manufacturer.
5. Forward a copy of this Safety Notice and the FSNs to all relevant personnel within your organisation or to any other organisations/persons to which/whom these devices have been transferred.
6. Report any concerns regarding these devices and any adverse incidents associated with these devices to CooperVision Manufacturing Ltd and the HPRA.

The HPRA advises that **consumers:**

1. Refer to the dedicated recall website and follow the instructions provided.
2. Cease use and dispose of any affected product as instructed.
3. Contact your healthcare professional with any health concerns.
4. Report any concerns regarding these devices or any adverse incidents involving these devices to CooperVision Manufacturing Ltd and the HPRA.

TARGET GROUPS

Consumers Distributors Eye Care Practitioners Opticians	Optometrists Purchasing Managers Retailers Supplies Managers
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BACKGROUND

Hy-Care Solution is a multi-purpose solution intended for the care of all soft contact lenses as a disinfecting solution, a daily cleaner, lens rinsing, lubricating and wetting agent, lens deposit removal and storage solution.

CooperVision Manufacturing Ltd has become aware that Hy-Care® contact lens solution may not offer appropriate levels of disinfection in some circumstances against high levels of *Candida Albicans* or an equivalent yeast organism. If the contact lens solution is unable to adequately disinfect the contact lens, there is an increased risk to the user of exposure to these particular types of microorganisms, which could lead to eye infections. Fungal infections of the eye are rare; however, they can be serious, requiring medical intervention.

CooperVision Manufacturing Ltd is performing a recall of all devices supplied to the market.

MANUFACTURER / AUTHORISED REPRESENTATIVE CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

CooperVision Manufacturing Limited,
South Point, Hamble,
Southampton,
SO31 4RF,
United Kingdom

Telephone: +44 1489883000 / +44 7929672861

E-mail: cdawson@coopervision.co.uk

Website: <https://coopervision.co.uk/practitioner>

Enquiries to the **authorised representative** should be addressed to:

CooperVision CL Kft,
Gorcsev Iván Street 7, Building C,
Gyál,
2360,
Hungary

Telephone: +36 30-285 5288

E-mail: ztoke@hu.coopervision.com

Website:

HPRA CONTACT INFORMATION

All **adverse incidents** relating to a medical device should be reported to:

Health Products Regulatory Authority
Kevin O'Malley House,
Earlsfort Centre,
Earlsfort Terrace,
Dublin 2

Telephone: +353-1-6764971

E-mail: devicesafety@hpra.ie

Website: www.hpra.ie

