

Safety Notice

Medical Devices

TOP-Q Super Fine Line



TOP-Q Super Derm Line



TOP-Q Super Deep Line



Priority 2 – Warning

HPRA Safety Notice: SN2020(10)

Issue Date: 13th August 2020

MANUFACTURER / SUPPLIER	HPRA CASE REFERENCE
Hi-Tech or Qufu Hi-Tech Trading Co. Ltd., China.	MS44379

ISSUE

The HPRA has become aware that the dermal fillers TOP-Q Super Fine Line, TOP-Q Super Derm Line and TOP-Q Super Deep Line have been placed on the Irish market with a falsely applied CE mark and therefore the safety of these dermal fillers cannot be assured. The use of these dermal fillers may result in unexpected effects or complications.

ACTION OR RECOMMENDATIONS

The HPRA advises the public to:

1. Contact the HPRA and your GP if you think a TOP-Q dermal filler has been (or may have been) used on you.

The HPRA advises that beauticians and healthcare professionals:

1. Do not buy these dermal fillers from any supplier, including websites / online sales.
2. Do not use these dermal fillers on clients or patients.
3. If identified, do not use any remaining stock and quarantine immediately.
4. Notify the HPRA of any suspected or confirmed use of the TOP-Q dermal filler products.
5. Notify the HPRA of any suspected or confirmed incidents following the use of the TOP-Q dermal fillers on patients or clients.

TARGET GROUPS

Beauticians / Beauty Therapists
Plastic surgeons
Distributors
Aestheticians

Dermatologists
Cosmetic surgeons
GPs
Members of the Public

BACKGROUND

Dermal fillers with an intended medical purpose or medical claim are considered to be medical devices and are classified under a high risk category. Dermal fillers must undergo a conformity assessment by a designated Notified Body to ensure that they are safe and perform as intended.

The HPRA understands that the TOP-Q Super Fine Line, TOP-Q Super Derm Line and TOP-Q Super Deep Line have not undergone assessment by a designated Notified Body and the CE mark has therefore been falsely applied to the products. As these products do not comply with the appropriate legislation, their safety cannot be assured. The HPRA has previously communicated on these products in December 2016 via HPRA Safety Notice SN2016(44).

The HPRA notes that there are other products in the TOP-Q Dermal Filler range, including the TOP-Q Super Dermal Filler and Top-Q Super Ultra Deep Line. To date, these products have not been found on the Irish market, however if you have these products, we advise you contact the HPRA.

The HPRA encourages anyone who has information or concerns about dermal fillers which do not appear to meet the requirements of the medical devices legislation to provide details of the device in question to the HPRA.

HPRA CONTACT INFORMATION

All **adverse incidents** and **non-compliant medical device issues** should be reported to:

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

Telephone: +353-1-6764971
Fax: +353-1-6344033
E-mail: devicesafety@hpra.ie
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