

EC Design Examination Certificate

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the design of the medical device(s):

**Sterile, Surgical non-absorbable Polyester Sutures
with specifications listed in the appendix**

of the manufacturer:

**Henry Schein Inc.
135 Duryea Road
Melville, NY 11747
United States of America**

fulfills the below mentioned requirements of the **Council Directive 93/42/EEC**:

Annex II, section 4


This certificate assumes that MEDCERT has to be informed about any changes of the approved design. Changes need further approval by MEDCERT.

For the placing on the market of medical devices covered by this certificate, a separate EC certificate of conformity according to Annex II without section 4 of Council Directive 93/42/EEC is required.

This certificate is valid until 27 May 2024

Report No.: 13820IA01F
Process No.: PP – 13820
Certificate No.: 13820GB411190930

Hamburg, 30 September 2019


MEDCERT Certification Body
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

Form F10010009e EN / Rev. 5 / 2019.05.22



Benannt durch/Designated by
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Appendix of EC Design Examination Certificate

Process No.: PP – 13820
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Specifications**Sterile, Surgical non-absorbable Polyester Sutures**

Sterile non-absorbable surgical sutures for general soft tissue approximation and/or ligation, including use in cardiovascular, ophthalmic and neurological procedures.

Material:	Polyester
Colour:	White (undyed) and Green
Construction:	Braided
Size	USP 2-0 to 5-0
Length.	30 cm to 75 cm
Needle.	Needled and non-needed
Sterilisation:	Irradiation or Ethylene Oxid

– End of appendix –

This appendix is integral part of the above-referenced certificate.
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