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SQA 02240-1	Technical Documentation File SEIRIN ACUPUNCTURE NEEDLE	060515	Sugiyama	060514	8	1. 1
Reason for Updating: Along with the page composition change, all the page revisions.						

1. Scope of application

The document covers the application of 「SEIRIN ACUPUNCTURE NEEDLE (SEIRIN Acupuncture Needles and Disposable SEIRIN Acupuncture Needles) manufactured by SEIRIN Corporation

2. Essential Requirement

It is conformable as a conclusion.

The Essential Requirement conformity check list (additional information 5)

3. Classification

SEIRIN Acupuncture Needles belong to Class II a of rule 6 for Invasive Instruments of MDD 93/42/EEC Annex IX (additional information 4)

4. Information about the accident

A person in charge understands our company overseas sales division in the European Community by the SQA14100 complaint treatment regulation, and makes contact with the administrative authorities.

5. Procedures for evaluating compatibility

Procedures for evaluating compatibility should follow the procedures stated in MDD93/42/EEC Annex VII and Annex V.

6. EC Representative

Name; 3B Scientific GmbH

Address; Rudorffweg 8, 21031 Hamburg, Germany

7. Clinical data

The present medical instruments are in general use. Their safety is guaranteed by their previous record of use. Records of shipments over the past three years (April 1994 – March 1997) and the number of complaints concerning quality (major categories derived from product specifications) are indicated below. (For details, refer to records of complaint processing records.)

Year	1994	1995	1996
No. of quality complaints (PPM)	0	0	0
Shipment records (no.)	129,820,000	148,205,000	167,303,000

It is conformed that SEIRIN Acupuncture Needles do not have any serious side effect and it works correctly as an acupuncture needle by additional information 8).

References 17 3)) are reports of the side-effects from using acupuncture needles. Side-effects are thought to be preventable. In addition, their rate of incidence is much lower than the side-effects attributable to medicines.

No reports of serious side-effects from acupuncture needles have been reported to SEIRIN Kasei Co., Ltd, which has been selling disposable acupuncture needles since 1980. As a result of these findings, there are no problems with SEIRIN Acupuncture Needles in terms of biological compatibility, safety, or clinical effectiveness.

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8. NotifiedBody

Name ; TÜV Product Service GmbH

Address ; Ridlerstrasse 65, D-80339 München Germany

9. Outline products

9.1 Application

SEIRIN Acupuncture Needles are instruments used in acupuncture therapy. They are intended to be used as they are without modification limited to one application only. These needles should be used only by physicians , acupuncture therapists , or other qualified persons.

9.2 General Explanation of product

SEIRIN Acupuncture Needles consist of three main parts: needle body, needle grip, and needle guidetube. For product details, refer to Document SQA 02211, entitled "SEIRIN Acupuncture Needles" and "Disposable SEIRIN Acupuncture Needles," which states product specification.

9.3 Product history

1980: Began manufacturing and sales of the world's first sterile, disposable acupuncture needles after receiving the approval of manufacturing from the Ministry of Health and Welfare.

SEIRIN Acupuncture Needles manufacturing Approval certificate : 15500BZZ00805000

1981: Established SERIN Deutschland and began selling disposable acupuncture needles in the European market.

1989: Established SERIN America and began selling disposable acupuncture needles in the North American market. and other's sale of 3million.

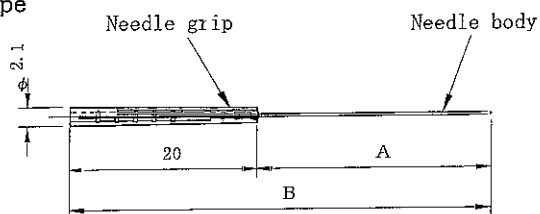
1993: Received the approval of the Ministry of Health and Welfare for manufacturing Disposable SERIN Acupuncture Needles. Manufacturing approval certificate : 20500BZZ0052000

1997: Sales reach approximately 14 millions units per month, consisting of domestic sales of 5 million units per month, European sales of 6million units per month, and North American and other's sale of 3million units per month.

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Reason for Updating; deletion of Soft and BEC Along with the page composition change, all the page revisions						

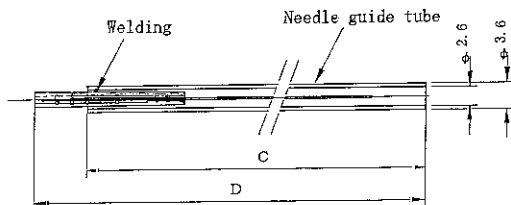
9.4 Outline diagram of product

Btype, Dtype



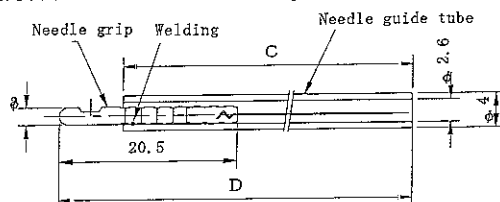
Needle length (mm)		Total needle length(mm)	
A		B	
15	±1	35	±1
30		50	
40		60	
50		70	
60		80	

Ctype



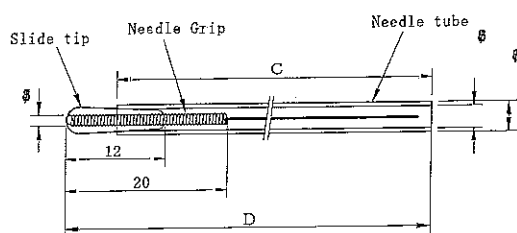
Needle length (mm)		Length of needle guide tube (mm)		Product length(mm)
A		C		D
30	±1	46	+0.5 -0	53
40		56		63
50		66		73
60		76		83

Jtype (those products destined for Germany from November 1997 on will only be known as C type)



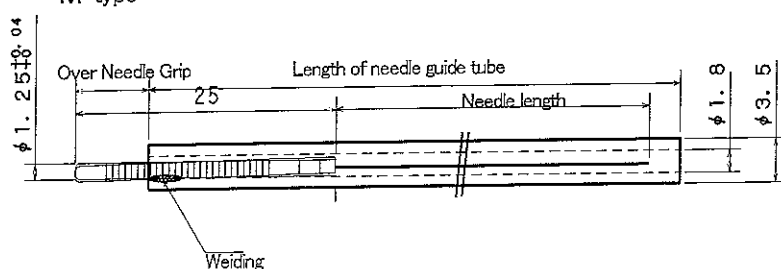
Needle length (mm)		Length of needle guide tube (mm)		Product length(mm)
A		C		D
30	±1	46	+0.5 -0	53
40		56		63
50		66		73
60		76		83

Ltype



Needle length (mm)		Length of needle guide tube (mm)		Product length(mm)
A		C		D
30	±1	46	+0.5 -0	52
40		56		62
50		66		72
60		76		82

M type



Needle length (mm)		Length of needle guide tube (mm)		Over Needle Grip (mm)
30	±1	51.4	+0.5 -0	65±1.0
40		61.4		
50		71.4		

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9.5 Application methods

- (1) Disinfect the skin at the point of needle insertion.
- (2) Open the blister packaging and take out the acupuncture needle. Be careful not to damage the tip of the needle when doing so. (In the case of needles with attached tubes, separate the needle guide tube from the joint portion of the needle gripe and insert the needle up to the needle guide tube at the proper location without removing the guide tube.)
- (3) Insert the needle and stimulate it. (In the case of needles with attached guide tubes, lightly tap the needle grip to open the skin, and insert the needle after removing the needle guide tube.)

9.6 Expiry of period of application :

the product is limited to use within 37 months after manufacture(after sterilization).

9.7 Product lines

1. Types

- ① Needle without tube B type: for Germany
D type: for domestic and North America
- ② Needle with guide tube C type: for Germany, for domestic and North America
J type: for domestic and North America (for Germany)
L type: for domestic and North America
M type: for domestic and North America

type /specification	needle grip	Needle guide tube	Method of joining needle body with needle grip
J type	Plastic	Present	Insert configuration
		Absent	
C type	Plastic	Present	Epoxy-one liquid adhesive
L type	Metal		Laser welding
M type	Metal		Press
B,D type	Plastic	Absent	Epoxy-one liquid adhesive

2. Size

NO. \square ($\square \times \square$)
a b c

a. Needle number(nomenclature)

b. Needle diameter (ϕ mm)

c. needle length (mm)

		needle length(mm)				
Needle number	Needle diameter (mm)	15	30	40	50	60
NO.02	0.12mm	○	○	○		
NO.01	0.14	○	○	○		
NO.1	0.16	○	○	○	○	
NO.2	0.18	○	○	○	○	○
NO.3	0.20	○	○	○	○	○
NO.4	0.23	○	○	○	○	○
NO.5	0.25	○	○	○	○	○
NO.8	0.30		○	○	○	○
NO.10	0.35			○	○	○

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14.2 Checklist of label content

Because it is difficult to display the manufacturer name to product itself by the restriction of a/the product form, production method etc., it has displayed it in the following packing material

Label item	Seal paper	Inner carton	Exterior carton	Comments
1.Name of manufacturer	○*	○	○	* only trade mark
2.Same as above; address		○	○	
3.Name and address of manager in charge within EC region.		○	○	
4.Name of product	○	○	○	
5.Product name, variety, size.		○	○	
6.Volume		○	○	
7.[STERILE]	○	○	○	symbol mark
8.[LOT]	○	○	○	
9.Date of expiration for use.	○	○	○	
10.Single Use	○	○	○	symbol mark
11.Precautions in storage or handling		○		
12.Explanation of use.		○		
13.Warnings, precautions		○		
14.Sterilization method	○	○	○	symbol mark

14.3 Originally proposed labels:

indicated on attachment 7).

14.4 Label control:

Figure symbol that I use to the labeling of an/the EN980 medical treatment device is complied with production lot and date of expiration of use to be imprinted on label materials. For details, refer to Identification Control Regulations (SQA 08100).

14.5 Traceability:

products should be traceable according to the lot of raw materials used in that lot and the production history. For details, refer to Identification Control Regulations (SQA 08100) and DHR.

14.6 Package functions(according to EN 868):

individual packaging materials (sealing paper and film) should exhibit no problems in microbial barrier test (data appended). No problem has been seen on the sterility preservation as shown in the validation data on sealing condition and sealing state. No problems with sterility test data of samples stored longer than the period of use (4 years). (For details, refer to storage sample test data.) Daily control should consist of checks of the exterior of the seals and their peelability.

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15. Sterilization

15.1 Sterilization conditions

1) The kind of the method of the sterilization

EO Gas

2) The method of the asepsis guarantee

Carry out Validation about the sterilization in accordance with the sterilized Validation standard (EN550;1994).

15.2 Sterilized vessel operation condition

① Sterile warranty level: SAL: 10^{-6}

② Gas types: A gas mixture consisting of 20% E.O. Gas and 80% CO₂.

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16. Bio-compatibility (based on ISO 10993)

No other parts of SERIN Acupuncture Needle than the needle body make incisions of human body.

The Biocompatibility Test of the needle body has shown no problem.

Technical Report No. 01/237-7. 059/01e

17. References

- 1) A Single-blind Investigation of Four Auricular Needle Puncture Configurations, American Journal of Chinese Medicine, Vol. XXIII, No. 2, pp. 105-114 (1995)
- 2) Improvement of Visual Acuity by Acupuncture Treatments: Report of Three Cases, Journal of Meiji Acupuncture Medicine, No. 7, pp. 49-53 (1990)
- 3) Nebenwirkungen bei der Akupunktur, Der Schmerz, H. Strzyz and G. Ernst, 11, pp. 13-19 (1997)
- 4) Literature Survey of Reported Adverse Effects Associated with Acupuncture Treatment, American Journal of Acupuncture, Vol. 24, No. 1, pp. 27-34 (1996)
- 5) The Use of Body Acupuncture for Treatment of Alcohol Dependence and Withdrawal Syndrome: A Controlled Study, American Journal of Acupuncture, Vol. 24, No. 1, pp. 19-25 (1996)

18. Additional information

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|--|--|
| 1) Declaration of conformity | *****total page 1 (→Japanese version) |
| 2) CE - mark certification | *****total page 4 (→Japanese version) |
| 3) List of CE Marked Product | *****total page 2 |
| 4) Classification | *****total page 1 |
| 5) Essential Requirement conformity check list | *****total page 5 |
| 6) Risk management file | ***** total page 18 |
| 7) Originally proposed labels | *****total page 16 (→Japanese version) |
| 8) Products using check list | *****total page 6 (→Japanese version) |
| 9) Articles | |
| | ***** ①total page 5 (→Japanese version) |
| | ***** ②total page 3 (→Japanese version) |
| | ***** ③total page 5 (→Japanese version) |
| | ***** ④total page 5 (→Japanese version) |
| | ***** ⑤total page 5 (→Japanese version) |

List of CE marked Product

EC-Rep : 3B Scientific GmbH

SEIRIN ACUPUNCTURE NEEDLE				
Type	LOT	Standard of classification		Note :
B type No.3($\phi 0.20 \times 15$ mm)	30811~	Invasive, Rule6	II a	
B type No.5($\phi 0.25 \times 40$ mm)	30821~	"	"	
B type No.8($\phi 0.30 \times 30$ mm)	30808~	"	"	
B type No.8($\phi 0.30 \times 50$ mm)	30804~	"	"	
B type No.10($\phi 0.35 \times 50$ mm)	30619~	"	"	
C type No.1($\phi 0.16 \times 30$ mm)	30901~	"	"	
C type No.5($\phi 0.25 \times 40$ mm)	30818~	"	"	
C type No.8($\phi 0.30 \times 50$ mm)	30723~	"	"	
Soft type No.8($\phi 0.30 \times 30$ mm)		"	"	
J type No.02($\phi 0.12 \times 30$ mm)	40116~	"	"	
J type No.02($\phi 0.12 \times 40$ mm)	41109~	"	"	
J type No.01($\phi 0.14 \times 30$ mm)	31224~	"	"	
J type No.01($\phi 0.14 \times 40$ mm)	40723~	"	"	
J type No.1($\phi 0.16 \times 30$ mm)	31205~	"	"	
J type No.1($\phi 0.16 \times 40$ mm)	31022~	"	"	
J type No.1($\phi 0.16 \times 50$ mm)	40727~	"	"	
J type No.2($\phi 0.18 \times 30$ mm)	31105~	"	"	
J type No.2($\phi 0.18 \times 40$ mm)	31205~	"	"	
J type No.2($\phi 0.18 \times 50$ mm)	40726~	"	"	
J type No.3($\phi 0.20 \times 30$ mm)	30912~	"	"	
J type No.3($\phi 0.20 \times 40$ mm)	30806~	"	"	
J type No.3($\phi 0.20 \times 50$ mm)	31107~	"	"	
J type No.3($\phi 0.20 \times 60$ mm)	40825~	"	"	
J type No.5($\phi 0.25 \times 30$ mm)	30829~	"	"	
J type No.5($\phi 0.25 \times 40$ mm)	31114~	"	"	
J type No.5($\phi 0.25 \times 50$ mm)	31205~	"	"	
J type No.5($\phi 0.25 \times 60$ mm)	41018~	"	"	
J type No.8($\phi 0.30 \times 30$ mm)	31104~	"	"	
J type No.8($\phi 0.30 \times 40$ mm)	30724~	"	"	
J type No.8($\phi 0.30 \times 50$ mm)	31003~	"	"	
J type No.8($\phi 0.30 \times 60$ mm)		"	"	
BEC type No.5($\phi 0.25 \times 30$ mm)		"	"	
BEC type No.8($\phi 0.30 \times 30$ mm)		"	"	
BEC type No.3($\phi 0.20 \times 30$ mm)		"	"	

List of CE marked Product

EC-Rep : 3B Scientific GmbH

SEIRIN ACUPUNCTURE NEEDLE					
Type		LOT	Standard of classification		Note :
L type	No.3 (ϕ 0.20 \times 30 mm)	30930 ~	Invasive, Rule6	II a	
L type	No.3 (ϕ 0.20 \times 40 mm)	30926~	"	"	
L type	No.3 (ϕ 0.20 \times 50 mm)	50107~	"	"	
L type	No.3 (ϕ 0.20 \times 60 mm)		"	"	
L type	No.4 (ϕ 0.23 \times 30 mm)		"	"	
L type	No.4 (ϕ 0.23 \times 40 mm)	50108~	"	"	
L type	No.4 (ϕ 0.23 \times 50 mm)	50108~	"	"	
L type	No.5 (ϕ 0.25 \times 30 mm)	30819~	"	"	
L type	No.5 (ϕ 0.25 \times 40 mm)	31006~	"	"	
L type	No.5 (ϕ 0.25 \times 50 mm)	50113~	"	"	
L type	No.5 (ϕ 0.25 \times 60 mm)	31224~	"	"	
L type	No.8 (ϕ 0.30 \times 30 mm)		"	"	
L type	No.8 (ϕ 0.30 \times 40 mm)	50111~	"	"	
L type	No.8 (ϕ 0.30 \times 50 mm)	50209~	"	"	
L type	No.8 (ϕ 0.30 \times 60 mm)	31112~	"	"	
M type	No.1 (ϕ 0.16 \times 30 mm)	60214~	"	"	JAPAN only
M type	No.1 (ϕ 0.16 \times 40 mm)	60214~	"	"	JAPAN only
M type	No.1 (ϕ 0.16 \times 50 mm)	60214~	"	"	JAPAN only
M type	No.2 (ϕ 0.18 \times 30 mm)	60316~	"	"	JAPAN only
M type	No.2 (ϕ 0.18 \times 40 mm)	60316~	"	"	JAPAN only
M type	No.2 (ϕ 0.18 \times 50 mm)	60315~	"	"	JAPAN only

Preparation April 3, 2006

Preparation	Confirmation	Approval
