

Certificate of Analysis

02/03/2023

LS.

The Sterility Assurance Products produced by SP Medikal San Ltd Sti are checked during and after production to comply with the specifications as laid down in their related Technical Data Sheets and the ISO and EN standards.

This Certificate of Analysis is valid for the following products:

Description

Indicator strip Steam 132 C- 20 min, Type 4

Art.nr.	Lot.No.	Exp. Date.
104.220.0500	13354	2027-12

The product has been undergoing tests to show it to be compliant to the following standard(s):

ISO 11140-1 2014:

**Sterilization of health care products -- Chemical indicators -- Part 1:
General requirements - Type 4 Indicator**

The outcome of the test(s) which have been conducted as part of our ISO 13485 Quality Management System is that the product is compliant and was released by the management for distribution and sales.


Seda Kücükylmaz
Quality Department


Peter M. den Uil (B. Sc.)
Managing Partner

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This Certificate of Analysis is valid for the following products:

Description

Indicator strip Steam 121C- 15 min / 134C- 4,0 min, Type 4

Art.nr.	Lot.No.	Exp. Date.
104.004.0500	13355	2027-12

The product has been undergoing tests to show it to be compliant to the following standard(s):

ISO 11140-1 2014:

**Sterilization of health care products -- Chemical indicators -- Part 1:
General requirements - Type 4**

The outcome of the test(s) which have been conducted as part of our ISO 13485 Quality Management System is that the product is compliant and was released by the management for distribution and sales.


Seda Kücükylmaz
Quality Department


Peter M. den Uil (B. Sc.)
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This Certificate of Analysis is valid for the following products:

Description

Indicator strip Steam 134C- 5,0 min, Type 4

Art.nr.
104.005.0500

Lot.No.
13356

Exp. Date.
2027-12

The product has been undergoing tests to show it to be compliant to the following standard(s):

ISO 11140-1 2014:

**Sterilization of health care products -- Chemical indicators -- Part 1:
General requirements - Type 4**

The outcome of the test(s) which have been conducted as part of our ISO 13485 Quality Management System is that the product is compliant and was released by the management for distribution and sales.



Seda Kücükylmaz
Quality Department



Peter M. den Uil (B. Sc.)
Managing Partner

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This Certificate of Analysis is valid for the following products:

Description

Indicator strip Steam 134C- 18,0 min, Type 4

Art.nr.	Lot.No.	Exp. Date.
104.018.0500	13358	2027-12

The product has been undergoing tests to show it to be compliant to the following standard(s):

ISO 11140-1 2014:

**Sterilization of health care products -- Chemical indicators -- Part 1:
General requirements - Type 4**

The outcome of the test(s) which have been conducted as part of our ISO 13485 Quality Management System is that the product is compliant and was released by the management for distribution and sales.


Seda Kücükylmaz
Quality Department


Peter M. den Uil (B. Sc.)
Managing Partner

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This Certificate of Analysis is valid for the following products:

Description

Indicator strip Steam 134C- 20,0 min, Type 4

Art.nr.	Lot.No.	Exp. Date.
104.120.0500	13359	2027-12

The product has been undergoing tests to show it to be compliant to the following standard(s):

ISO 11140-1 2014:

**Sterilization of health care products -- Chemical indicators -- Part 1:
General requirements - Type 4 Indicator**

The outcome of the test(s) which have been conducted as part of our ISO 13485 Quality Management System is that the product is compliant and was released by the management for distribution and sales.


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Quality Department


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This Certificate of Analysis is valid for the following products:

Description

Indicator strip Steam 121C- 20 min / 134C- 7,0 min, Type 4

Art.nr.	Lot.No.	Exp. Date.
104.007.0500	13357	2027-12

The product has been undergoing tests to show it to be compliant to the following standard(s):

ISO 11140-1 2014:

**Sterilization of health care products -- Chemical indicators -- Part 1:
General requirements - Type 4**

The outcome of the test(s) which have been conducted as part of our ISO 13485 Quality Management System is that the product is compliant and was released by the management for distribution and sales.


Seda Kücükylmaz
Quality Department


Peter M. den Uil (B. Sc.)
Managing Partner