



THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

*SQS has issued an IQNet recognized certificate that the organization:*

**Hygiene360 AG**

**Büelstrasse 17**

**8330 Pfäffikon ZH**

**Switzerland**

*has implemented and maintains a*

**Management System**

*for the following scope(s):*

**Production and distribution of cleaning, disinfection  
and hygiene products for medical and dental markets**

*which fulfills the requirements of the following standard(s):*

**EN ISO 13485:2016 Medical devices – Quality Management System**

*Issued on: 2018-05-02*

*Expires on: 2021-05-01*

*This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as  
a stand-alone document*

**Registration Number: CH-40407**



**Alex Stoichitoiu**  
**President of IQNet**

**Felix Müller**  
**CEO SQS**



**IQNet Partners\*:**

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\* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under [www.iqnet-certification.com](http://www.iqnet-certification.com)

SQS as a conformity assessment body identification number 1250 herewith certifies the company

## Hygiene360 AG

Büelstrasse 17

8330 Pfäffikon ZH

Switzerland

the use of a quality assurance system in its design, development, manufacturing and distribution which fulfills the requirements set out in:

### ANNEX II

### Directive 93/42/EEC (without section 4)

This approval is based on the result of the audit documented in the report dated April 23, 2018.

The scope of validity covers the products

**Cleaning, disinfection and hygiene products for medical and dental markets**

The following CE label can be applied to the products mentioned in the Appendix of this certificate

**CE 1250**

A condition for the validity of this certificate is a regular examination in accordance with Annex II.5 of the Directive 93/42/EEC.

Validity 02.05.2018–01.05.2021  
Issue 11.06.2019

Reg. no. 41851  
Approved Medical Responsible  
02.05.2018



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



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Swiss Association for Quality and  
Management Systems SQS  
Bernstrasse 103, 3052 Zollikofen, Switzerland



Swiss Made

Partner of  






THE INTERNATIONAL CERTIFICATION NETWORK

# CERTIFICATE

*SQS has issued an IQNet recognized certificate that the organization:*

**Hygiene360 AG**

**Büelstrasse 17**

**8330 Pfäffikon ZH**

**Switzerland**

*has implemented and maintains a*

**Management System**

*for the following scope(s):*

**12, 29**

*which fulfills the requirements of the following standard(s):*

**ISO 9001:2015 Quality Management System**

*Issued on: 2018-05-02*

*Expires on: 2021-05-01*

*This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document*

**Registration Number: CH-43927**



**Alex Stoichitoiu**  
*President of IQNet*

**Felix Müller**  
*CEO SQS*

**SQS**



**IQNet Partners\*:**

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IRAM Argentina JQA Japan KFQ Korea MIRTEC Greece MSZT Hungary Nemko AS Norway NSAI Ireland  
NYCE-SIGE México PCBC Poland Quality Austria Austria RR Russia SII Israel SIQ Slovenia  
SIRIM QAS International Malaysia SQS Switzerland SRAC Romania TEST St Petersburg Russia TSE Turkey YUQS Serbia  
IQNet is represented in the USA by: AFNOR Certification, CISQ, DQS Holding GmbH and NSAI Inc.

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# Certificate

SQS herewith certifies that the company named below has a management system which meets the requirements of the standard specified below.



**Hygiene360 AG**  
**Büelstrasse 17**  
**8330 Pfäffikon ZH**  
**Switzerland**

Scope of certification

**Whole enterprise**

Field of activity

**Production and distribution of cleaning, disinfection  
and hygiene products for medical and dental markets**

Normative base

**ISO 9001:2015**

**Quality Management System**



Scope(s) 12, 29

Validity 02.05.2018–01.05.2021

Reg. no. 43927

Issue 02.05.2018

*X. Edelmann*

X. Edelmann, President SQS

*F. Müller*

F. Müller, CEO SQS



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Swiss Association for Quality and  
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Bernstrasse 103, 3052 Zollikofen, Switzerland



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## ANNEX V

## Directive 93/42/EEC

This Appendix is valid only in connection with the following certificate:

Registration Number 40408

Validity from May 2, 2018 up to and including May 1, 2021

**This approval includes the following Medical Device/s:**

Hygiene360 AG Products

Disinfectants for surfaces of medical devices (medical equipment, installations and instruments)

Class IIa

PROSEPT® Foam

PROSEPT® Floor

PROSEPT® Floor XL

PROSEPT® Sensi

Disinfectants for medical and dental instruments

Class IIa

PROSEPT® Contra

Disinfectants for dental aspirating units and amalgam separators

PROSEPT® Jet D

Disinfectants for dental impression materials

Class IIa

PROSEPT® Impression

PROSEPT® Impression S

Appendix issue date: May 2, 2018



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Management Systems SQS  
Bernstrasse 103, 3052 Zollikofen, Switzerland



Swiss Made

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**IONet**



SQS as a conformity assessment body identification number 1250 herewith certifies the company

**Hygiene360 AG**  
**Büelstrasse 17**  
**8330 Pfäffikon ZH**  
**Switzerland**

the use of a quality assurance system in its manufacturing and distribution which fulfills the requirements set out in:

## ANNEX V

## Directive 93/42/EEC

This approval is based on the result of the the report dated April 23, 2018.

The scope of validity covers the products

**Cleaning, disinfection and hygiene products  
for medical and dental markets**

The following CE label can be applied to the products mentioned in the Appendix of this certificate

**CE 1250**

A condition for the validity of this certificate is a regular examination in accordance with Annex V.4 of the Directive 93/42/EEC



Validity 02.05.2018–01.05.2021  
Issue 02.05.2018

Reg. no. 40408  
Approved Medical Responsible  
02.05.2018



F. Müller, CEO SQS



D. Taddeo, Medical Responsible



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Swiss Association for Quality and  
Management Systems SQS  
Bernstrasse 103, 3052 Zollikofen, Switzerland



Partner of  


## ANNEX II

### Directive 93/42/EEC (without section 4)

This Appendix is valid only in connection with the following certificate:

Registration Number 41851

Validity from May 2, 2018 up to and including May 1, 2021

**This approval includes the following Medical Device/s:**

Hygiene360 AG Products

Disinfectants for surfaces of medical devices (medical equipment, installations and instruments)

Class IIb

PROSEPT® Spray

PROSEPT® Wipes

PROSEPT® Jumbo Wipes

Disinfectants for medical and dental instruments

Class IIb

PROSEPT® Burs

PROSEPT® Pera

PROSEPT® Fortis

Appendix issue date: June 11, 2019



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