

# Certificate

Certificate  
**17894 - M**

**kiwa**

Valid from 2026-04-16 Last change date 2026-04-16  
First issue date 2020-05-21 Valid until 2029-05-20

## ISO 13485:2016

### Quality Management System Certificate

We certify that the Quality Management System of the Organization:

## Telemis SA

is in compliance with the standard UNI CEI EN ISO 13485:2021 for the following products/services:

Design, development and placing on the market of PACS (Picture Archive and communications System) Medical software.  
Distribution and provision of services of PACS (Picture Archive and Communication System) Medical software.

Kiwa Cermet Italia S.p.a.  
Medical Devices  
Director  
Alessia Frabetti



The maintaining of the certification is subject to annual surveillance and dependent on the observance of Kiwa Cermet Italia contractual requirements.  
This certificate is composed of 2 pages. The following technical sheet provides details of the scope of certification.

#### Telemis SA

##### Registered Headquarters

Avenue Athéna 2 1348 Ottignies-Louvain-la-Neuve - Belgium

##### Certified sites

For details on the sites, please refer to the attached Technical Data Sheet

Kiwa Cermet Italia S.p.A.  
Società con socio unico,  
soggetta all'attività di direzione e  
coordinamento di Kiwa Italia  
Holding S.r.l.  
Via Cadrano, 23  
40057 - Granarolo dell'Emilia (BO)  
T. +39. 051.4593.111  
F. +39. 051.763.382  
it.info@kiwa.com  
[www.kiwa.it](http://www.kiwa.it)



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## Data sheet attached to the Certificate

### ISO 13485:2016

#### Certified sites:

##### TELEMIS SA

#### Registered Headquarters:

Avenue Athéna 2 1348 Ottignies-Louvain-la-Neuve - Belgium

#### Certified sites:

Avenue Athéna 2 1348 Ottignies-Louvain-la-Neuve - Belgium

Design, development and placing on the market of PACS (Picture Archive and communications System) Medical software.

Distribution and provision of services of PACS (Picture Archive and Communication System) Medical software.

##### TELEMIS SA

#### Registered Headquarters:

Route des Falaises 7 CH 2000 Neuchatel - Switzerland

#### Certified sites:

Route des Falaises 7 CH 2000 Neuchatel - Switzerland

Distribution and provision of services of PACS (Picture Archive and Communication System) Medical software.

##### TELEMIS FRANCE SAS

#### Registered Headquarters:

7 Rue Jean Monnet ZA Casse II - 31240 Saint Jean - France

#### Certified sites:

7 Rue Jean Monnet ZA Casse II - 31240 Saint Jean - France

Distribution and provision of services of PACS (Picture Archive and Communication System) Medical software.

##### TELEMIS S.r.l.

#### Registered Headquarters:

Via Sansovino 217 - 10151 Torino - Italy

#### Certified sites:

Via Sansovino 217 - 10151 Torino - Italy

Distribution and provision of services of PACS (Picture Archive and Communication System) Medical software.

##### TELEMIS GmbH

#### Registered Headquarters:

Madrider Straße 25, 41069 Mönchengladbach - Germany

#### Certified sites:

Madrider Straße 25, 41069 Mönchengladbach - Germany

Distribution and provision of services of PACS (Picture Archive and Communication System) Medical software.

##### TELEMIS INTERNATIONAL SA

#### Registered Headquarters:

13 Rue Route d'Esch 1470 Luxembourg

#### Certified sites:

Avenue Du Swing, 7 – 4367 Esch Belval - Luxembourg

Design, development of PACS (Picture Archive and communications System) Medical software.

[Kiwa Cermet Italia S.p.A.](#)  
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