

# Certificate

**mdc medical device certification GmbH**  
certifies that

**GAEDE Medizinsysteme GmbH**  
**Im Moos 6**  
**79112 Freiburg**  
**Germany**

for the scope

**development, production, distribution and servicing of  
imaging and measuring systems for nuclear medicine**

has introduced and applies a

**Quality Management System**

The mdc audit has proven that this quality management system  
meets all requirements of the following standard

**EN ISO 13485**

**Medical devices – Quality management systems –  
Requirements for regulatory purposes**

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2020-01-22
Valid until	2022-11-17
Registration no.	D1280300005
Report no.	P19-01262-155626
Stuttgart	2020-01-22



Head of Certification Body



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# EC Certificate

**mdc medical device certification GmbH**

Notified Body 0483  
herewith certifies that

**GAEDE Medizinsysteme GmbH  
Im Moos 6  
79112 Freiburg  
Germany**

for the scope

**gamma cameras and nuclear medical processing systems  
(GKS-1, GKS-2000, GKS-2000 Cardiac and GMS-586)**

has introduced and applies a

**Quality System**

for the design, manufacture and final inspection.

The mdc audit has proven that this quality system  
meets all requirements according to

**Annex II – excluding Section 4  
of the Council Directive 93/42/EEC**

of 14 June 1993 concerning medical devices.

The surveillance will be held as specified in Annex II, Section 5.

Valid from	2020-01-22
Valid until	2024-05-26
Registration no.	D1280300004
Report no.	P19-01262-155622
Stuttgart	2020-01-22



Head of Certification Body

