

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

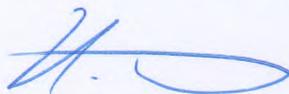
The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2012 + AC:2012 - ISO 13485:2003 + Cor. 1:2009

Valid from	2016-11-18
Valid until	2019-11-17
Registration no.	D1280300001
Report no.	P16-01203-79482
Stuttgart	2016-11-18



Head of Certification Body



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.

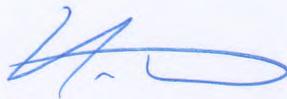
The mdc audit has proven that this quality system
meets all requirements according to

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	2016-11-18
Valid until	2021-11-17
Registration no.	D1280300002
Report no.	P16-01203-79486
Stuttgart	2016-11-18



Head of Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
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