CERTIFICATE

for the

Quality Assurance System

As a notified body of the European Union (Reg. No. 0124) DEKRA Certification GmbH hereby approves the Quality Assurance System applied for design, manufacture and final inspection by the company

Contract Medical International spol. S.r.o.

Vazni 848 • 50003 Hradec Kralove, Czech Republic

Approval is based on the decision dated 27.05.2009 and the result of the report no. 51240-Z1-00 and is performed in accordance with the stipulations of

Annex II, Section 3 of the Directive 93/42/EEC

of the Council dated June 14, 1993 governing medical devices. The certification is applicable to the devices specified in the Annex. The devices in question are subjected to testing and examination in accordance with Annex II, Section 3 of the Directive 93/42/EEC. The listed devices may be affixed with the CE marking indicated below.

CE 0124

Date of the first certification:	27.05.2009	Date of the last recertification:	--.--.----
This certificate is valid until:	26.05.2014	Certificate-registration No.:	51240-16-00 English version (duplicate)

DEKRA Certification GmbH
Stuttgart, 27.05.2009

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 •

Akkreditiert durch
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
ZLG-ZQ-992.94.16

Annex to the Certificate 51240-16-00 dated 27.05.2009

English version

Revision status: 1 Date: 20.11.2009

Devices/device categories included in the certificate

Class III:

- Occlutech Figula® PFO- and ASD-Occluder N
- Figulla® Flex PFO- and ASD-Occluder

DEKRA Certification GmbH • D-70565 Stuttgart, Handwerkstraße 15 •
DEKRA
DEKRA Certification