EC Certificate

mdc medical device certification GmbH

Notified Body 0483 herewith certifies that

Gerium Medical Ltd. 6, Ha-Kishon Street Yavne, 8122017 Israel

for the scope

BiliCare (non-invasive transcutaneous bilirubinometer)

has introduced and applies a

Quality System

for the aspects of manufacture concerned with the conformity of the products with metrological requirements.

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 Valid until
 2018-04-04

 Valid until
 2023-04-03

 Registration no.
 D1355800008

 Report no.
 P18-00164-113696

Stuttgart 2018-04-03

Head of Certification Body





Internet: http://www.mdc-ce.de