

EC Design Examination Certificate

The Notified Body

**MEDCERT Zertifizierungs- und Prüfungsgesellschaft für die Medizin GmbH
Pilatuspool 2 – 20355 Hamburg – Germany**

herewith certifies that the design of the medical device(s):

REVISIO® RTM

with specifications listed in the appendix

of the manufacturer:

**AQ Solutions GmbH
An der Hasenkaule 10
50354 Hürth
Germany**

fulfills the below mentioned requirements of the **Council Directive 93/42/EEC**:

Annex II, section 4

This certificate assumes that MEDCERT has to be informed about any changes of the approved design. Changes need further approval by MEDCERT.

For the placing on the market of medical devices covered by this certificate, a separate EC certificate of conformity according to Annex II without section 4 of Council Directive 93/42/EEC is required.

Effective date: 2020-01-25

Expiry date: 2024-05-27

Report No.: 13971IA01F

Process No.: PP – 13971

Certificate No.: 13971GB411200120

Hamburg, 20 January 2020



MEDCERT Certification Body
(Lorenz Runge)

The certificate is only valid when provided entirely with all of its pages.
To verify the validity of this certificate, contact info@medcert.de.

MEDCERT Identification Number: 0482

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Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
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Appendix of EC Design Examination Certificate

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Specifications

Metall head						
16000128	16000132	16000136	16000228	16000232	16000236	16000328
16000332	16000336	—	—	—	—	—

ALL-POLY-PATELLA						
27700010	27700020	27700030	—	—	—	—

REVISIO® RTM Trochanteric replacement endofemoral C						
60045003	60045004	60045005	60045006	60045007	60045103	60045104
60045105	60045106	60045107	60045203	60045204	60045205	60045206
60045207	60045303	60045304	60045305	60045306	60045307	—

REVISIO® RTM Cone adapter						
60046011	60046012	60046013	60046015	60046016	60046017	60046019
60046020	60046021	60046022	60046023	60046024	60046025	60046026
60046027	60046028	—	—	—	—	—

REVISIO® RTM Stem C						
60048011	60048012	60048013	60048014	60048015	60048016	60048111
60048112	60048113	60048114	60048115	60048116	60048211	60048212
60048213	60048214	60048215	60048216	60048311	60048312	60048313
60048314	60048315	60048316	60048411	60048412	60048413	60048414
60048415	60048416	60048511	60048512	60048513	60048514	60048515
60048516	—	—	—	—	—	—

REVISIO® RTM condylar replacement						
60049001	60049002	60049003	60049004	60049005	60049006	60049007
60049008	60049009	60049010	60049011	60049012	60049013	60049014
60049015	60049016	60049017	60049018	60049019	60049020	60049021
60049022	60049023	60049024	60049025	60049026	60049027	—

REVISIO® RTM Trochanteric replacement						
60050007	60050008	60050009	60050010	—	—	—

REVISIO® RTM Tibial head						
60054001	60054002	60054003	60054101	60054102	60054103	—

REVISIO® RTM Extensio Module						
60055030	60055040	60055050	60055060	60055080	60055120	60055160
60056030	60056040	60056050	60056060	60056080	60056120	60056160

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REVISIO® RTM Connector						
60057001	60057002	60057003	60057004	60057005	60057006	60057007
60057008	—	—	—	—	—	—

REVISIO® RTM Connector endofemoral						
60057009	60057010	60057014	—	—	—	—

REVISIO® RTM Connector Arthrodesis						
60057011	60057012	60057013	—	—	—	—

REVISIO® RTM Locking screw						
60058001	60058002	—	—	—	—	—

REVISIO® RTM Locking screw Arthrodesis						
60058003	60058004	—	—	—	—	—

REVISIO® RTM Locking Screw Tibial augment						
60058008	60058010	60058012	60058016	60058020	—	—

REVISIO® RTM Endofemoral Module						
60059100	60059101	60059102	60059103	60059104	60059105	60059106
60059107	60059108	60059109	60059110	60059111	60059112	60059113
60059114	60059115	60059116	60059117	60059118	60059119	60059120
60059121	60059122	60059123	60059124	60059125	60059200	60059201
60059202	60059203	60059204	60059205	60059206	60059207	60059208
60059209	60059210	60059211	60059212	60059213	60059214	60059215
60059216	60059217	60059218	60059219	60059220	60059221	60059222
60059223	60059224	60059225	—	—	—	—

REVISIO® RTM Femoral box endofemoral						
60060001	60060002	60060003	60060004	60060101	60060102	60060103
60060104	—	—	—	—	—	—

REVISIO® RTM Femoral joint module endofemoral						
60061001	60061002	60061003	60061004	60061101	60061102	60061103
60061104	—	—	—	—	—	—

REVISIO® RTM Femoral tibial stem C long						
60062201	60062202	60062203	60062204	60062205	60062206	60062301
60062302	60062303	60062304	60062305	60062306	—	—

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REVISIO® RTM Arthrodesis spacer						
60063000	60063025	60063050	60063125	60063150	60063300	60063325
60063350	60063425	60063450	—	—	—	—

REVISIO® RTM Tibial component						
60064001	60064002	60064003	60064004	60064005	60064006	—

REVISIO® RTM Tibial Plate						
60065101	60065102	60065103	60065104	60065105	60065106	—

REVISIO® RTM Tibial augment						
60066008	60066010	60066012	60066016	60066020	60066108	60066110
60066112	60066116	60066120	60066208	60066210	60066212	60066216
60066220	60066308	60066310	60066312	60066316	60066320	—

REVISIO® RTM Femoral tibial stem C short						
60067001	60067002	60067003	60067004	60067005	60067006	60067007
60067008	60067009	60067010	—	—	—	—

REVISIO® RTM Femoral component						
60071001	60071002	60071003	60071004	60071005	60071006	60071101
60071102	60071103	60071104	60071105	60071106	—	—

REVISIO® RTM Femoral box						
60072001	60072002	60072003	60072004	60072005	60072006	60072101
60072102	60072103	60072104	60072105	60072106	—	—

REVISIO® RTM Tibia Insert endofemoral rotating						
60073108	60073110	60073112	60073114	60073208	60073210	60073212
60073214	60073308	60073310	60073312	60073314	60073408	60073410
60073412	60073414	—	—	—	—	—

REVISIO® RTM Tibial Plate endofemoral rotating						
60074001	60074002	60074003	60074004	60074005	60074101	60074102
60074101	60074102	60074103	—	—	—	—

REVISIO® RTM Tibial stem						
60075001	60075002	60075003	60075004	60075005	60075101	60075102
60075103	60075104	60075105	—	—	—	—

– End of appendix –

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