Agreement
on the confidential handling of documents[1]

between

the **Foundation for Quality and Efficiency in Health Care**

represented by
the Director of the Institute for Quality and Efficiency in Health Care
(Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen, IQWIG)
Professor Dr. med. Jürgen Windeler

Im Mediapark 8 (KölnTurm)
50670 Köln, Germany

("IQWiG" in the following text)

and

COMPANY NAME
represented by

FUNCTION/POSITION
TITLE/NAME

STREET
POSTAL CODE, LOCATION

("COMPANY" in the following text)

Preamble

Within its remit to issue directives on the introduction of new examination and treatment methods according to §92 (1), Sentence 2, No. 5 Social Code Book (Sozialgesetzbuch, SGB) V, the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) awards commissions to IQWiG. This refers to, among other things, the assessment of examination and treatment methods according to §135 SGB V and the assessment of examination and treatment methods in hospitals according to §137c SGB V, which the G-BA is responsible for. According to §139a (3) SGB V, the results of the benefit assessment are also to be considered in the fulfilment of IQWG's other legal responsibilities such as patient information. In addition, according to §139a (4) SGB V, IQWiG must publicly report on its working processes and results in regular intervals, including the basis for decision-making.

Against this background, the COMPANY was asked by IQWiG to provide documents to IQWiG containing non-public information on the medical device. In principle, the COMPANY is willing to support IQWiG in the fulfilment of its tasks assigned by the legislator and the G-

[1] Translation of the German document: *Vereinbarung über die vertrauliche Behandlung von Unterlagen* (Status: 2 April 2015). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

BA. In order to adequately account for the COMPANY's trade and business secrets in this regard, the parties conclude the following agreement:

§1
Subject matter

This agreement exclusively regulates the issue regarding under which preconditions information provided by the COMPANY to IQWiG for the assessment of the respective medical device can be used by IQWiG and is allowed to be made accessible to third parties. Further rights and obligations are not justified by this agreement.

§2
Definition of terms

2.1 "Information" is all information, regardless of its form, provided by the COMPANY to IQWiG for the assessment of the medical device. Information provided by another company associated to the COMPANY is treated in the same way as confidential information provided by the COMPANY itself.

2.2 "Confidential information" is all information in the terms of §2.1 that is designated as confidential.

§3
Use of information

3.1 The information used by IQWiG in order to fulfil its legally-assigned tasks within the framework of benefit assessments and the subsequent tasks, such as the production of information for patients and physicians (including publications in scientific journals), is used exclusively according to the provisions of this agreement.

The use of information for other purposes requires the COMPANY's prior written approval.

3.2 IQWiG commits itself to only allow those employees as well as external experts it commissions to access the confidential information if these persons themselves have signed a written agreement with IQWiG on the confidential handling of confidential information following the stipulations of the present agreement.

§4
Step-by-step process

4.1 First step

4.1.1 A two-step process is envisaged for the transfer of information to IQWiG. In the first step, the COMPANY provides IQWiG with an overview of all studies it has available on the medical device under assessment.

4.1.2 For the studies provided to IQWiG, the COMPANY uses the table formats specified by IQWiG.

4.2 Second step

If IQWiG requires more detailed information on the documents transferred according to §4.1 for the assessment, it informs the COMPANY in writing, specifying the precise designation of the COMPANY's studies. The COMPANY can choose the following formats for the transfer of information to IQWiG, as far as they are available:

a) summaries of study reports, according to Appendix 1 of guideline ICH E3 (http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002832.pdf), provided they fulfil the requirements of the CONSORT statement

or

b) reports from study results registries, provided the information contained fulfils the requirements of the CONSORT statement (CONSORT checklist without items 20 to 22 [discussion/interpretation; generalizability and overall evidence])

or

c) documents prepared for IQWiG – the content must fulfil the requirements of the CONSORT statement (CONSORT checklist without items 20 to 22 [discussion/interpretation; generalizability and overall evidence])

as well as

d) documents with data separately requested by IQWiG on single study parameters going beyond letters a) to c)

4.3 Publication

4.3.1 With the exception of the naming of the studies listed, as well as the short description of the studies mentioned in the overview of the list of studies, the confidential information transferred according to §4.1 of this agreement is to be kept confidential.

4.3.2 The information transferred according to §4.2 of this agreement, in particular data from study reports (but not in the format of study reports) are allowed to be published within the framework of IQWiG's obligation according to §139a (4) SGB V. If the COMPANY informs IQWiG that information is to be published in scientific journals, within the framework of its reports IQWiG will only publish a short description of the study in German as well as those data considered in the assessment.

4.3.3 If the COMPANY transfers further confidential information to IQWiG, then these data are not allowed to be published without the COMPANY's prior written approval. In this context it is clear to the COMPANY that the methods and summarized results of scientific studies do not represent trade and business secrets and are thus published in the justification of IQWiG's recommendation.

§5
Appropriation

5.1 Fulfilment of tasks

The information is provided exclusively with the aim of supporting IQWiG in fulfilling its tasks assigned by the legislator according to §139a (3) and (4) SGB V and by the G-BA within the framework of the G-BA's execution of its responsibilities according to §§135, 137c and 137e SGB V. Any other use of the information outside of this appropriation is prohibited.

5.2 No granting of licence

The provision of information does not represent a granting of a licence or other permission for the commercial or non-commercial use of the confidential information by IQWiG and/or third parties. In particular, the provision of information does not mean approval for the use of the information by third parties, especially within the framework of the conformity assessment procedure according to the EU directives 90/385/EWG, 93/42/EWG and 98/79/EG.

§6
Duration of contract

6.1 The agreement becomes effective when signed and is concluded for an unlimited period.

6.2 The parties have the right of ordinary termination of the contract with a period of 30 days. In this case, however, IQWiG has the right to further use and publish information that has already been transferred by the COMPANY, with adherence to the rules described in this agreement.

§7
Other issues

7.1 To become effective, changes or extensions to this agreement require a written form. This also applies to the waiving of the requirement of a written form.

7.2 This agreement is subject to German law.

For IQWiG:

Köln, _____ _____

(Date) (Signature)

Professor Dr. Jürgen Windeler, Director of the Institute

For the COMPANY:

Location, _____ _____

(Date) (Signature)

[Name; Position]

Location, _____ _____

(Date) (Signature)

[Name; Position]