Justification by notified bodies in case of divergent views between the notified body and the expert panel in the context of clinical evaluation and performance evaluation consultation procedures (CECP, PECP)

1. Purpose of this document and legal provisions

This document is aimed at structuring the full justification that notified bodies shall provide in case of divergent views between them and the expert panel in the context of the clinical evaluation consultation procedure (CECP) or performance evaluation consultation procedure (PECP).

As regards the **CECP**, Article 55(1) of Regulation (EU) 2017/745 (MDR) provides: "*A notified body shall notify the competent authorities of certificates it has granted to devices for which the conformity assessment has been performed pursuant to Article 54(1). Such notification [...] shall include the summary of safety and clinical performance pursuant to Article 32, the assessment report by the notified body, the instructions for use [...], and, where applicable, the scientific opinion of the expert panels [...].* ***In the case of divergent views between the notified body and the expert panels, a full justification shall also be included****".*

Moreover, Annex IX, Section 5.1, point (g), MDR provides: *"The notified body shall give due consideration to the views expressed in the scientific opinion of the expert panel. [...]* ***The notified body shall provide a full justification where it has not followed the advice of the expert panel in its conformity assessment report*** *and the Commission shall without prejudice to Article 109 make both the scientific opinion of the expert panel and the written justification provided by the notified body publicly available via Eudamed".*

As regards the **PECP**, Article 50(1) of Regulation (EU) 2017/746 (IVDR) provides: *"A notified body shall notify the competent authority of certificates it has granted for class D devices [...]. Such notification [...] shall include the instructions for use [...], the summary of safety and performance [...], the assessment report by the notified body, and, where applicable, the laboratory tests and the scientific opinion by the EU reference laboratory [...], and where applicable the views expressed in accordance with Article 48(4) by the experts [...].* ***In the case of divergent views between the notified body and the experts, a full justification shall also be included****."*

Important notice:
The notified body's justification provided in the context of the CECP will be published on the European Commission's expert panel website[1] (in the absence of Eudamed) and, once fully functional, via Eudamed (Annex IX, Section 5.1, point (g) MDR). The notified body's justification provided in the context of the PECP will not be published.

2. Information to be provided

In order to allow a clear identification of the scientific opinion issued by the expert panel in the framework of the CECP or of the views expressed by the experts in the framework of the PECP, the notified body should provide before the actual justification at least the following administrative information:

Notified body name and number	*BSI NL 2797*
CECP or PECP dossier number	EMA/EX/0000228672
Expert panel name	Orthopaedics, traumatology, rehabilitation, rheumatology
Date of expert panel opinion or view	*2024/11/09*

[1] https://ec.europa.eu/health/medical-devices-expert-panels/experts/list-opinions-provided-under-cecp_en

BSI has now issued the MDR Certificate (Reference MDR766966) for the Zimmer Identity Shoulder (DUE) (Opinion Reference EMA-EX-0000228672). BSI has a divergent view from the Expert Panel, as noted below.

Expert Panel Opinion:
Section 2.4 Recommendations

In summary the DUE brings novelty to the market, particularly with regard to the additional stem adapter. The expert panel retains concerns about the equivalence analysis and the lack of clinical evidence with the DUE as described in previous sections. Given the expert panel's concerns on the equivalence analysis, premarket clinical evidence with the DUE should be provided.

Notified Body divergent view:

The assessment performed by the notified body at the time of submission to the expert panels was based on equivalence. The notified body was satisfied with this equivalence claim. After the opinion was issued, and at the time of certificate recommendation, further data was presented by the manufacturer which included the assessment of additional benchmark device data, preliminary clinical data from an ongoing clinical study with the DUE, as well as DUE PMS data. These data were not available to the Notified Body at the time of the expert panel submission and thus were not available to the expert panel for the CECP. This further determined that there is sufficient evidence to support a claim of equivalence with the requirements of EU MDR 2017/745 Annex XIV Part A for all technical, biological and clinical considerations, therefore reliance on premarket clinical evidence was not considered necessary.