
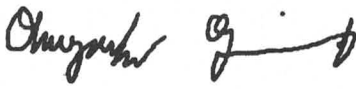

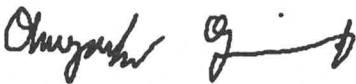


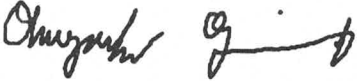
<p>REF</p> <p>All products</p> <p>Page1 from 1</p>	<p>ANNEX 1 to Declaration of conformity from 23.05.2022</p> <hr/> <p>ANNEX FROM 24/05/2024</p>	
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Subject	Description of the change(s)
Information on extending the validity of the declaration of conformity in accordance with Regulation (EU) 2024/1860	<p>In accordance with Regulation (EU) 2024/1860, the conformity of the products named in the declaration of conformity can be extended depending on the class to be assigned in future under Regulation (EU) 2017/746:</p> <p>for products of the</p> <ul style="list-style-type: none"> <li>– Class D until 31 December 2027</li> <li>– Class C until 31 December 2028</li> <li>– Class B until 31 December 2029</li> </ul> <p>subject to an application to a Notified Body for certification in accordance with Regulation (EU) 2017/746, which</p> <p>for products of the</p> <ul style="list-style-type: none"> <li>– Class D until 26/05/2025</li> <li>– Class C until 26/05/2026</li> <li>– Class B until 26/05/2027</li> </ul> <p>and the existence of a resulting contract to be concluded by 26 September of the respective year.</p>
Certificate numbers mentioned on the declaration of conformity	Updating the certificate number from D1415300015_QMS 13485 according to D1415300028_QMS 13485 (Expires 2027-05-09)
Evaluation of the change(s)	
According to MDCG document 2022-6, the changes described above do not constitute significant changes to the design or intended use of the products named in the declaration of conformity dated 23 May 2022. The Declaration of Conformity dated 23 May 2022 therefore remains valid, <b>taking into account the changes described above.</b>	
<p>Neckargemünd, 2024-05-24</p> <div style="text-align: right; margin-right: 100px;">  </div> <p>Signature PRRC (Angela Grajek):</p>	

REF All products Page1 from 1	ANNEX 2 TO DECLARATION OF CONFORMITY FROM 23.05.2022 <hr/> ANNEX FROM 15/08/2024	
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Subject	Description of the change(s)
Clarification on the involvement or non-involvement of the notified body	For the devices mentioned in <b>list A and B of Annex II</b> of Directive 98/79/EC, the manufacturer has applied the procedure according to Annex IV of the same Directive (EC declaration of conformity, full quality assurance system) <b>with the involvement of the notified body</b> , for all other devices the procedure <b>according to Annex III of the same Directive</b> (EC declaration of conformity) <b>without the involvement of the notified body</b> .
<b>Evaluation of the change(s)</b>	
According to MDCG document 2022-6, the change described above does not constitute a significant change in the design or intended use of the products mentioned in the declaration of conformity dated 23 May 2022. The declaration of conformity dated 23 May 2022 therefore remains valid, <b>taking into account the change described above.</b>	
<b>Neckargemünd, 2024-08-15</b>  Signature PRRC (Angela Grajek):	

REF All products Page1 from 1	ANNEX 3 TO DECLARATION OF CONFORMITY FROM 23.05.2022 <hr/> ANNEX FROM 03/02/2025	
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Subject	Description of the change(s)
Correction	The conformity for the product "Alsever's solution, Art. no. 41160, according to the declaration of conformity dated 23 May 2022 - declared for Directive 98/79/EC - has lapsed, as it was classified as a Class A product according to Regulation (EU) 2017/746 and its conformity to Regulation (EU) 2017/746 was declared by means of its own declaration of conformity from 2022.
<b>Evaluation of the change(s)</b>	
According to MDCG document 2022-6, the change described above does not constitute a significant change in the design or intended use of the products mentioned in the declaration of conformity dated 23 May 2022. The declaration of conformity dated 23 May 2022 therefore remains valid, <b>taking into account the change described above.</b>	
<b>Neckargemünd, 2025-02-03</b> <div style="text-align: right; margin-right: 100px;">  </div> Signature PRRC (Angela Grajek):	