



**NOTIFICATION**

*Addendum*

The following communication, dated , is being circulated at the request of the delegation of Brazil.

**Title:** Resolution - RDC number 750, 06 September 2022

<b>Reason for Addendum:</b>	
<input type="checkbox"/>	Comment period changed - date:
<input type="checkbox"/>	Notified measure adopted - date:
<input type="checkbox"/>	Notified measure published - date:
<input type="checkbox"/>	Notified measure enters into force - date:
<input type="checkbox"/>	Text of final measure available from <sup>1</sup> :
<input type="checkbox"/>	Notified measure withdrawn or revoked - date: Relevant symbol if measure re-notified:
<input type="checkbox"/>	Content or scope of notified measure changed and text available from <sup>1</sup> : New deadline for comments (if applicable):
<input type="checkbox"/>	Interpretive guidance issued and text available from <sup>1</sup> :
<input checked="" type="checkbox"/>	Other: The notified measure had its validity period extended until 31 March 2024. <a href="http://antigo.anvisa.gov.br/documents/10181/6485985/RDC_781_2023_.pdf/f641a5f9-54b0-43b0-b1b0-3466e15209c8">http://antigo.anvisa.gov.br/documents/10181/6485985/RDC_781_2023_.pdf/f641a5f9-54b0-43b0-b1b0-3466e15209c8</a>

**Description:** Resolution - RDC number 750, 06 September 2022 - previously notified through G/TBT/N/BRA/1444 -, which establishes a temporary optimized analysis procedure, in which the analyzes conducted by an Equivalent Foreign Regulatory Authority are used for the verified analysis of the market authorization and post-market authorization petitions of medicines, biological products and their inputs, and the letter of adequacy of the pharmaceutical ingredient dossier active, had its validity period extended until 31 March 2024 by Resolution- RDC number 781, 16 March 2023.

The final text is available only in Portuguese and can be downloaded at:

[http://antigo.anvisa.gov.br/documents/10181/6485985/RDC\\_781\\_2023\\_.pdf/f641a5f9-54b0-43b0-b1b0-3466e15209c8](http://antigo.anvisa.gov.br/documents/10181/6485985/RDC_781_2023_.pdf/f641a5f9-54b0-43b0-b1b0-3466e15209c8)

<sup>1</sup> This information can be provided by including a website address, a pdf attachment, or other information on where the text of the final/modified measure and/or interpretive guidance can be obtained.

