

**TO WHOM IT MAY CONCERN**

Basel , 03 May 2023

**HERCEPTIN® 600 mg Solution for Injection (Ro 45-2317/F07)**

The nominal weight (without overfill) per vial HERCEPTIN 600 mg is:

Trastuzumab (drug substance):	600 mg
Excipients:	427 mg
Water:	<u>4288 mg</u>
<b>Total:</b>	<b>5315 mg</b>

Each vial contains an overfill of approximately 9%. Therefore the weight including the overfill is:

Trastuzumab (drug substance):	Excipients:	654 mg
Water:		465 mg
<b>Total:</b>		<u>4674 mg</u>
		<b>5793 mg</b>

The density of the solution at 20 °C is 1.063 g/mL.

On behalf of Roche Registration GmbH,

ppa.



Christelle Laroche  
Pharma Technical Regulatory

ppa.



Dr. Markus Boutellier  
Pharma Technical Regulatory

**Roche Registration GmbH**

Emil-Barell-Straße 1  
D-79639 Grenzach-Wyhlen  
Germany  
Telefon +49 7624 14 2892  
Telefax +49 7624 1015

Sitz der Gesellschaft:  
Grenzach-Wyhlen  
Registergericht:  
Freiburg HRB 717155

Geschäftsführung:  
Dr. Julia Wagle  
USt-IdNr.: DE314809599