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To whom it may concern

DIVISION Medical Devices

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OUR REF 91.31-23795/24

National Competent Authority Report (NCAR) according to Regulation (EU) 2017/745 or Directive 98/79/EC

DE-BfArM-2024-07-30-4754 BfArM case number: 23795/24

Dear Sir or Madam

Please find enclosed a National Competent Authority Report, in accordance with the relevant Regulation or Directive.

Enquiries should be submitted to the Federal Institute for Drugs and Medical Devices (BfArM), Medical Devices Division, e-mail:

md-vigilance@bfarm.de.

Please inform us about changes in your e-mail address.

Yours faithfully

Medical Devices Division

On behalf of the Federal Institute for Drugs and Medical Devices

This letter was created electronically and is valid without signature.

Attachment: NCAR DE-BfArM-2024-07-30-4754