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Our reference: INS-484230-100803248-17666325

INSPECTION OF THIRD COUNTRY SOURCE PLASMA / RECOVERED PLASMA SITES [Redacted]

We refer to the inspection performed for your company at
Canadian Plasma Resources, Unit #180
6325 Gateway Blvd NW
Edmonton, AB, T6H 5H6, Canada
premises on 19 April 2022 by the Federal Office for Safety in Healthcare (BASG).

On the basis of the inspection and subsequent correspondence, we can confirm that operations relating to the safety and quality of plasma are in general compliance with the requirements of Commission Directives 2004/33/EC and 2005/62/EC implementing Directive 2002/98/EC of the European Parliament and of the Council, the relevant European Pharmacopoeia Monograph(s) and Directive 2003/94/EC.

This letter reflects the status of the plasma collection site at the time of the inspection noted above. The Issuing Authority has established appropriate inspection and control measures for the above named site(s) to deem it compliant until **July 2023**. This letter should not be relied upon to reflect the compliance status if the above mentioned date has been exceeded, after which the issuing authority should be consulted.

Any matters arising from this inspection will be reviewed at the next inspection.

Due to the restrictions caused by COVID-19, this statement of next inspection was issued in line with EMA recommendation EMA/INS/GMP/534269/2018 "Application of inspection and control measures to facilitate risk-based inspection planning of sites within the Plasma Master File (PMF) certification system". On-site inspections will resume as soon as there is a consensus that the period of the public health crisis has passed. The clarifying remark section of individual SONIs will indicate any exceptions. Competent authorities reserve the right to inspect a blood establishment should the need arise.

On behalf of the Austrian Federal Office for Safety in Health Care

Kraßnigg Andreas
am 1.9.2022