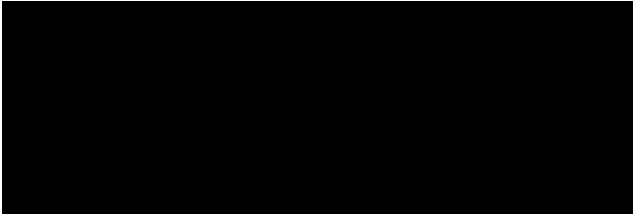


ZytoMed Systems GmbH | Anhaltinerstr. 16 | 14163 Berlin



Berlin, 12th September 2022

Important Notification for all Users!

It has come to our attention that the batch of product POLHRP-500K listed below has been given too long an expiry date.

Details of affected device:

Device name:	ZytoChem Plus (HRP) Polymer Kit	Catalogue number (REF):	POLHRP-500K
Lot:	195HR	Expiration Date:	2023-12-31

Advice on action to be taken by the user:

1. Immediately inspect all ZytoChem Plus (HRP) Polymer Kit in your possession, including partially used product, and identify those with the above listed lot number.
2. Please immediately discontinue use and distribution of the identified affected lot number. Follow the instructions below for product return.
3. Please complete the enclosed response form and send it to us by 30th September 2022 by email to international@zytomed-systems.de or by fax to +49 30 804 984 999 (att. Sicherheitsbeauftragter MPG).

Advice on product reshipment:

Please send the product to: ZytoMed Systems GmbH
Anhaltinerstr. 16
14163 Berlin

Please use one of the following courier services for collection. Customer ID:

GO!	32387
Trans-o-flex	138354000
UPS	009V3E

Actions taken by Zytomed Systems:

- Complete/ Partly (Batch recall) withdrawal of the product from the market

Remarks:

According to the legal regulations Zytomed Systems is liable to inform the Competent Authority about this corrective action. We ask you to send the completed response form to us by the date indicated above.

This notification is being made with the knowledge of the regulatory authorities. We apologize for any inconvenience this action may cause. Thank you for your attention and support in this matter.

In case of any questions or concerns, please do not hesitate to contact our customer service at +49 30 804 984-995 (Monday through Friday 07.00 am – 4.30 pm).

Sincerely,

Corrective Action Response Form

- I have inspected my inventory and identified the following quantities of the affected lot:
_____ of batch 195HR.

- I have quarantined inventory consisting of affected lot.

- Not applicable, as no material of the affected lot was identified.

- I have notified my customers that were shipped the affected product lot.

- Not applicable, as no sales to additional customers.

Place, date, signature

Print name

Facility name and address

Please email or fax the completed response form by **30th September 2022** to Zytomed Systems GmbH.

E-Mail: international@zytomed-systems.de

Fax: +49 30 804 984-999