VYGON
Value Life

VYGON - Prager Ring 100 - 52070 Aachen

[redacted]
Department Manager Quality Assurance
& Medical Device Surveillance

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Aachen, 08.05.2025

**Urgent FSCA on epicutaneo cava, Code 2184.00, Batch 020425GH – Recall 009**

As legal manufacturer of the affected article, we would like to inform you that we have identified a batch-related manufacturing problem at the catheter tube.

Due to a manufacturing fault during the assembly of the catheter, the catheter tube may be damaged in the area of the metal tube, which can result in a leakage at the blue junction to the extension line.

| Product Description | Code No. | Batch No. |
|---|---|---|
| epicutaneo cava | 2184.00 | 020425GH |

We therefore ask you to immediately withdraw these batches from services and to return them according to our instructions below.

Please acknowledge receipt of this letter and complete and return the attached form, indicating the quantities withdrawn from your institution.

Your National Competent Authority has been informed about this Recall.

If you should require further information, please contact your local Vygon distributor.

We apologize for any inconvenience this recall may cause.

Yours sincerely,

[redacted]

[redacted]

Department Manager Quality Assurance & Medical Device Surveillance

**Urgent FSCA on epicutaneo cava, Code 2184.00, Batch 020425GH – Recall 009**

**ACKNOWLEDGMENT AND CUSTOMER RESPONSE FORM**

**Please complete and return this form by e-mail to vigilance@vygon.com**

| | |
|---|---|
| **Name and address of the institution:** | |
| **Full name of the person to contact:** | |
| **Function:** | |
| **☎ Phone number:** | |
| **✉ E-mail:** | |

**We acknowledge receipt of the above FSCA and that the information contained in this field safety notice has been shared with all recipients / end users of above-mentioned products within our organization.**

**Please tick the appropriate box:**

**We have the following products available on stock:**

**Code 2184.00, Batch 020425GH**

❑Yes ❑ No If you have stock, number of units removed: _____

Signature and Date: _____

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WEEE-Reg-Nr.: DE49290163

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Ust-Ident-Nummer: DE 121 68 64 46
Amtsgericht Aachen HRB 28087

Sparkasse Aachen
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BIC Code: AACSDE 33

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Kto.-Nr. 0211 680 508 - (BLZ 370 100 50)
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BIC Code: PBNKDEFF370