

SUMMARY OF PHARMACOVIGILANCE SYSTEM

XEVMPPD Number: MFL3816

1. Contact Details of the Qualified Person for Pharmacovigilance (QPPV)

The QPPV of **Welding GmbH & Co. KG** resides and carries out her tasks in **Germany**.

Qualified Person for Pharmacovigilance (QPPV)	Name	Angelika Bredehorst
	Function	Regulatory Affairs & Pharmacovigilance
	Address	Esplanade 39, 20354 Hamburg, Germany
	Phone	
	Fax	
	24h availability	
	Email	

2. Pharmacovigilance System Master File (PSMF) Location

The PSMF is located in the EU at **Welding GmbH & Co. KG**, Germany, where the QPPV operates and the main pharmacovigilance activities are performed. The document outlines the routine pharmacovigilance activities that are carried out by **Welding GmbH & Co. KG** in collaboration with its license / distribution partners worldwide.

PSMF location	Name	Angelika Bredehorst
	Address	Esplanade 39, 20354 Hamburg, Germany
	Phone	
	Fax	
	Email	

3. Statement of the Applicant/MAH and the QPPV regarding their availability and the means to fulfil the tasks and responsibilities outlined in title IX of EU Directive 2001/83/EC

The signatories hereby declare that

- **Welding GmbH & Co. KG** has services available of a QPPV who is sufficiently trained and aware of the responsibilities outlined in EU Directive 2001/83/EC.
- **Welding GmbH & Co. KG** and the QPPV have the necessary means to fulfil the tasks and responsibilities as listed in title IX of EU Directive 2001/83/EC

Hamburg, 25.04.2013

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Dr. Torsten Knecht
Chief Executive Officer
Welding GmbH & Co. KG

Angelika Bredehorst
Qualified Person for Pharmacovigilance
Welding GmbH & Co. KG