To whom is this Med-Info applicable?
Medical Device manufacturers using human blood derivatives as specified in Annex I Medical Device Directive (MDD), section 7.4 – only where the substance is liable to act upon the body with action ancillary to that of the device.

What is required from manufacturers?
The documentation should be provided in CTD format. A guideline to the contents is to be found in MEDDEV 2.1.3 part B and C.

General information
- Description of the device (components, intended use)
- Justification for the use of blood derivatives (intended purpose, suitability of the substance, critical evaluation of alternatives)
- Critical evaluation of the results of the risk analysis (potential risk in relation to the expected benefit)

Qualitative and quantitative particulars of the constituents
- Description of the substance
- The amount included in the device
- If modifications were introduced, adequate description required

Description of method of manufacture
- Overall description of the device manufacturing process
- Process description for the substance is required

Controls of starting materials
- Specification of the blood derivate
- EU Pharm to be referenced (if applicable)
- National references (if applicable)
- Drug master file(s)

Control tests carried out at intermediate stages of the manufacturing process of the Medical Device
- In-process controls (if applicable)

Control tests on finished products
- Qualitative test(s)
- Quantitative test(s)

Stability
- Desired function to be maintained during shelf life
- Recommended storage conditions?

Toxicity
- Toxicological profile of the substance
- New substance: results of toxicity tests (ISO 10993)

Pharmacodynamics
- Intended action of the substance with regard to the Medical Device
Pharmacokinetics
- Description of the pattern of local and systemic exposure to the medicinal substance
- Maximum level and duration of exposure should be considered
- Potential level of exposure a safety concern?
- New substance: release characteristics, subsequent distribution, and elimination

Local tolerance
- Relevant results from ISO 10993 to be provided
- Where appropriate: relevant literature

Clinical documentation
- Clinical evaluation of the Medical Device is required.
  Relevant documents: see MEDDEV 2.7.1

Labeling
- Acc. MDD and the applicable standards

What is assessed by the Notified Body?
TÜV SÜD Product Service as a Notified Body will contact EMA for the initiation of the consultation procedure. The Notified Body performs the consultation procedure with EMA on behalf of the manufacturer. The electronically submitted documentation will include our verification of the usefulness of the substance as part of the Medical Device, taking into account the intended purpose of the device and the documentation on the human blood derivative compiled by the manufacturer. Our report will include an assessment of the risk management, the risk-benefit analysis with regard to the intended use of the product, and an evaluation of the performance and clinical benefit of the Medical Device as well as of the biocompatibility and biological safety. Based on this information, EMA will provide a scientific opinion on the quality and safety of the substance including the clinical risk-benefit profile of the incorporation of the human blood derivative into the device. When issuing its opinion, EMA shall take into account the manufacturing process and the data related to the usefulness of incorporation of the substance into the device as determined by the Notified Body.

After consultation a final report will be compiled taking into account the comments of the competent authority and the results of the performed assessments of other important product characteristics.

Links to informative websites
www.ema.europa.eu
www.pheur.org
www.pei.de
www.ich.org
www.ec.europa.eu (MEDDEV)

Your contact partner at TÜV SÜD Product Service can provide further information.

Dr. Ursula Lauer
Phone: +49 89 5008-4171
Email: ursula.lauer@tuev-sued.de