

# Sustainability & Product Compliance reimaged

Using SAP Data from and for the Value Chain

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What do  
**Sustainability**  
and  
**Material Compliance**  
have to deal with each other?

# Global Regulations regarding Sustainability & Material Compliance

POP

RoHS

ESPR

WEEE

BatterieG

REACH

TSCA

MDR

J-Moss  
Japan  
RoHS

CLP

PPWR

CP 65

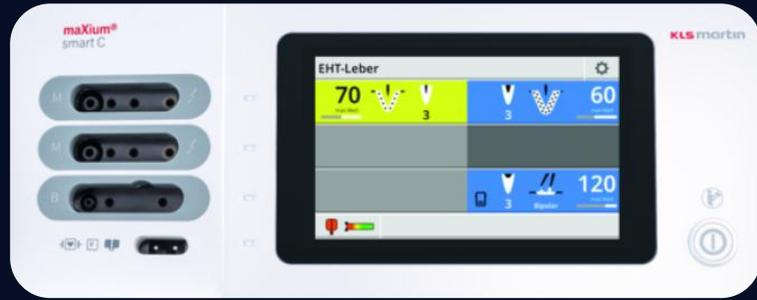
Conflict  
Minerals

China  
RoHS

LKSG

# What Regulations Apply to Electrical Medical Devices?

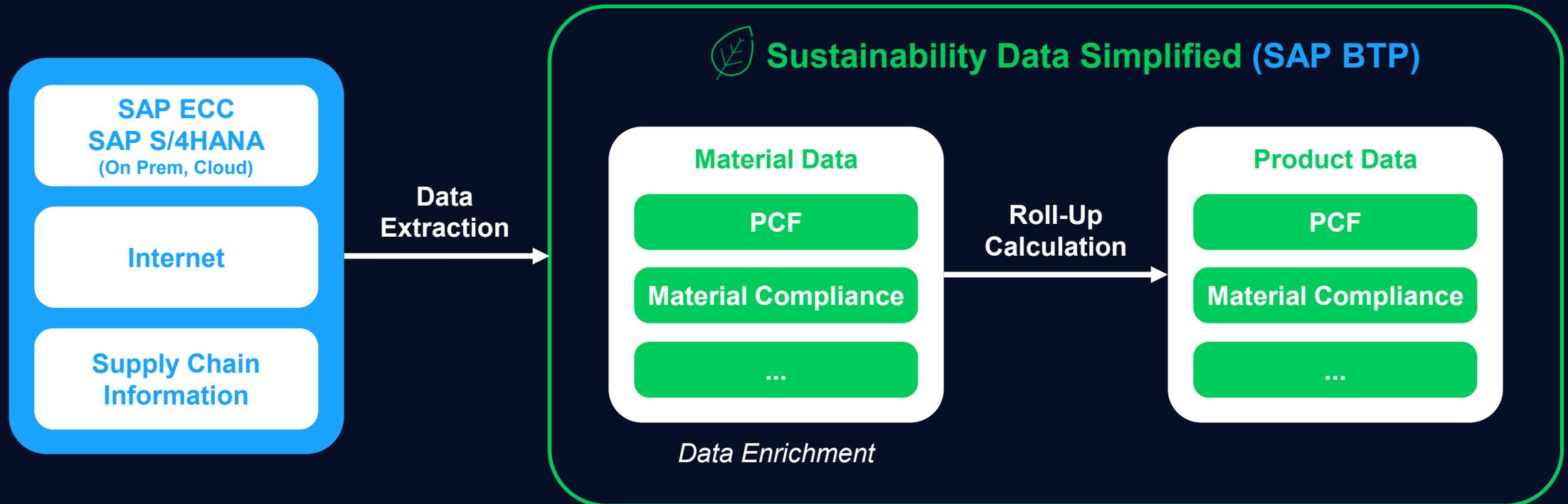
Example: Maxium Smart C – HF Generator by KLS Martin



**30+ regulatory requirements for a complex electrical medical device**

Regulation	Source	Mandatory
MDR Klassifikation & Docu	MDR (EU 2017/745), Anhang II/III	Mandatory in EU
Risk Management	ISO 14971	Mandatory in EU
UDI / EUDAMED	MDR, Art. 27–29	Mandatory in EU
Base Safety	IEC 60601-1	Mandatory in global
EMV	IEC 60601-1-2	Mandatory in global
HF-special	IEC 60601-2-2	Mandatory in global
Usability	IEC 60601-1-6 / IEC 62366-1	Mandatory in EU
Software	IEC 62304	Mandatory in EU
Labeling & Symbols	ISO 15223-1 / ISO 20417	Mandatory in EU
Chemicals-Compliance	REACH / RoHS	Mandatory in EU
SCIP-Notice	REACH, AbfallRRL	Mandatory in EU
Elektical Devides EoL	WEEE / ElektroG	Mandatory in EU
Battery	BattG	Mandatory in EU
Package	VerpackG / PPWR	Mandatory in EU
Quality Management	ISO 13485	Mandatory in global
Audits	MDR	Mandatory in EU
USA Submission	FDA 510(k)	Mandatory in US
CB-Report	IECEE CB-Scheme	Mandatory in global
China / Brasil / Canada	NMPA, ANVISA, Health Canada	Mandatory in CA/BR/CN

# Sustainability- & Compliance-Data from Purchase to Production



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